## Medi-Span Electronic Drug File (MED-File) v2

**Documentation Manual** 

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### **Contact Information**

Wolters Kluwer Clinical Drug Information 8425 Woodfield Crossing Boulevard, Suite 490 Indianapolis, Indiana 46240

www.wolterskluwerCDI.com

Phone: 855-633-0577

Sales E-mail: MS-salessupport@wolterskluwer.com

Published Date 11/11 Revised Date 04/18

## **Scope and Purpose**

MED-File v2 is intended to support customers by providing a codified drug dictionary, drug vocabulary, and drug pricing for prescription drugs and medication-based over-the-counter products in the United States. This *Documentation Manual* is intended to be the primary source for important information, including information about the scope and purpose of MED-File v2 content and its inherent limitations, that authorized users must understand before using the content.

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  warnings, precautions, allergic reactions, adverse reactions, FDAapproved or off-label indications, dosing regimens or duration of therapy
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- The MED-File v2 Licensing Agreement provides an update service to the database. These updates are essential to properly reflect current knowledge. Each edition of MED-File v2, therefore, includes an expiration date. Use of any edition of Medicaid Rebate File beyond the expiration date is specifically prohibited.
- MED-File v2 Documentation Manual is copyrighted by Clinical Drug Information, LLC. Use of copyrighted information is restricted to the terms of the Licensing Agreement.

## **Preface**

#### In This Preface...

Description
What The Documentation Manual Contains
Document Conventions
Information on Third-Party Products
Contacting Customer Support

## Description

MED-File v2 provides a name-based drug file that supports the terminology and data needs within the clinical marketplace.

This manual provides an introduction to MED-File v2 as well as information for successfully implementing the database.

## What The Documentation Manual Contains

The *Documentation Manual* contains the following chapters and appendices:

- Chapter 1, "Introduction," summarizes the purpose of the MED-File v2 and provides a brief background of the database.
- Chapter 2, "Editorial Policies," lists the sources of information for MED-File v2, and the editorial policies that are specific to this database.
- Chapter 3, "MED-File v2 Database Structure" explains the structure of the MED-File v2 data files, and provides a description of the reserve fields, date format, database layout, and data elements.
- Chapter 4, "MED-File v2 Data Elements" describes the files included with the MED-File v2, including the Copyright, Summary, Readme, Validation/ Translation, and so forth.
- Chapter 5, "Applications," provides information on how to use MED-File v2 in your application.
- Appendix A, "Loading and Updating," describes how to load and update files, and process the Summary, Supplements, Data Dictionary, and Validation/Processing files.
- Appendix B, "Record Layout Diagrams," contains record layout diagrams for your reference.

- Appendix C, "GPI Name Abbreviation," is a listing of GPI abbreviations.
- Appendix D, "Dosage Form Codes" contains the list of current values for Dosage Form.
- Appendix E, "Wolters Kluwer Clinical Drug Information's Therapeutic Classification System" lists the TCS listing. This listing is current at the time of this printing.

## **Document Conventions**

Document conventions are special features designed to help you understand information. This section describes the conventions that are used in the Documentation Manual.

## **Special Elements**

Wolters Kluwer Clinical Drug Information's Documentation Manuals use special elements to help you gain a greater understanding of the information being presented. This section illustrates the "Notes" special element and its use.

Notes: Notes are important points that you should understand. They offer important information, and they explain special circumstances. The following is an example of a note.

Note If the Field Type [Data Element Code C040] is "C", this field will always be "N".

## Information on Third-Party Products

Our databases are created at Wolters Kluwer Clinical Drug Information. Occasionally, products created by other companies are shipped with our databases. Because Wolters Kluwer Clinical Drug Information does not support products created by other companies, please contact the original manufacturer if you need assistance while using its product. If you need assistance while using any Wolters Kluwer Clinical Drug Information database, refer to the contact information in the next section.

## **Contacting Customer Support**

For support for MED-File v2 or any other Wolters Kluwer Clinical Drug Information database, contact Customer Support using one of the following methods:

- Call 1-655-633-0577
- Visit www.wolterskluwercdi.com/support

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## **Chapter 1: Introduction**

### In This Chapter

Permitted/Intended Use(s) Overview of the Database Features of the Database

### Permitted/Intended Use(s)

Medi-Span Electronic Drug File (MED-File) v2 is intended to support customers by providing a codified drug dictionary, drug vocabulary, and drug pricing for prescription drugs and medication-based over-the-counter products in the United States.

MED-File v2 is not intended to support medical supplies, durable medical equipment, non-human drugs (such as veterinary or other products), or health and beauty items.

#### **Overview of the Database**

MED-File v2 provides customers with drug data and terminology that supports the ever-changing world of drug information in healthcare.

MED-File v2 contains Wolters Kluwer Clinical Drug Information proprietary drug name concepts, external drug concepts, ingredient information, drug pricing, and numerous attributes about a drug designed to meet the needs of healthcare across a variety of settings.

In addition, MED-File v2 offers programming flexibility to end-users requiring drug product information. Drug product data elements can be accessed and combined to facilitate the following:

- medication order entry
- formulary development and maintenance
- dispensing activities
- prescription claims processing
- other health care applications requiring drug data

#### Features of the Database

The following are features of MED-File v2:

- includes prescription and over-the-counter drug products in the US using industry standard identifiers, including National Drug Code (NDC), Universal Product Code (UPC), and Health Related Item (HRI)
- provides Wolters Kluwer Clinical Drug Information's proprietary drug name-based concepts at varying levels of specificity, supporting the needs of healthcare professionals throughout their workflow
- includes Wolters Kluwer Clinical Drug Information's proprietary, hierarchical Therapeutic Classification System (TCS) that allows for identification of drug products at any of several levels including Drug Group, Drug Class, and Drug Subclass
- associates Wolters Kluwer Clinical Drug Information's proprietary concepts to NDCs, UPCs, and HRIs
- links old concepts to new concepts, enabling patient medication profiles and other applications to accurately depict the defined drug
- associates generic names to brand names
- includes a variety of drug product attributes that aid in drug product substitution (such as Therapeutic Equivalence Evaluation [TEE] Code, Multi-Source Code, and Brand Name Code)
- provides Wolters Kluwer Clinical Drug Information's proprietary Generic Product Packaging Code (GPPC) which generically defines a drug and its packaging
- includes upper and lower case drug names as well as alternative representations for the drug's dosage form and strength
- defines the drug's ingredients and their strengths, and indicates whether each ingredient is active or inactive
- includes current drug pricing for Average Wholesale Price (AWP), Direct Price (DP), Wholesale Acquisition Price (WAC), Centers for Medicare and Medicaid Services' Federal Upper Limit (CMS FUL)
- provides Average Average Wholesale Price (AAWP) and Generic Equivalent Average Price (GEAP) calculated by a proprietary Wolters Kluwer Clinical Drug Information algorithm
- defines manufacturers, labelers, and distributors for drug products
- includes inactive drug products for up to 48 months

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# Chapter 2: Editorial Policies

## In This Chapter

Introduction
Overview
Proprietary Drug Concepts
External Drug Concepts
Ingredients
Pricing
Drug Attributes

#### Introduction

This chapter outlines the editorial policies that guide the development of MED-File v2 by Wolters Kluwer Clinical Drug Information. Information regarding Wolters Kluwer Clinical Drug Information's proprietary and external concepts as well as data within MED-File v2 is also provided.

**Note** Not all data elements for MED-File v2 have editorial policies. Those that do are described in this chapter.

#### **Overview**

MED-File v2 covers a broad spectrum of pharmaceutical drug products, chemicals, over-the-counter (OTC) products, medical devices, supplies, and related items. Below is a summary of the types of products included in MED-File v2:

- Prescription Drug Products
- Medicated OTC Products
- Devices

#### Prescription Drug Products

Amebicides Antimalarials Gastrointestinal Agents
Analgesics Antineoplastics Genitourinary Products

Anesthetics Agents Antitubercular(s) Immunosuppressive
Anthelmintics Antivirals Neuromuscular Drugs
Antiasthmatics Biologicals Parenteral Solutions

Antibiotics Cardiovascular Agents Pediculicides
Anticoagulants Solutions CNS Drugs Peritoneal Dialysis

Antifungals Cough/Cold/Allergy Agents Prostaglandins
Antihistamines Decongestants Respiratory Agents

Antihyperlipidemic Diagnostic Agents Scabicides

Antihypertensives Diuretics Sclerosing Agents
Endocrine & Metabolic Drugs Topical Products

#### **Medicated OTC Products**

Allergy Products Contact Lens Solutions First Aid Supplies
Acne Products Cough/Cold Preparations Hemorrhoidal

Preparations

**Analgesics Denture Products** Laxatives **Antacids Diabetic Supplies** Minerals Anti-Diarrheals Diet Products **Nutrients Anti-Emetics Dietary Products** Nutritional **Anti-Fungals Products** Ear Products Oral Hygiene Asthma Products Electrolytes Shampoos Athletes Foot Preparations **Eye Products** Sleep Aids **Baby Products** Family Planning Products Toothpaste

Bath Products Feminine Hygiene Products Tube Feedings Vitamins

#### Devices

Bandages Female Personal Care Products Needles

Blood Administration Kits Heating Pads Optical Supplies
Condoms Incontinence Supplies Ostomy Supplies
Diabetic Supplies Infusion Pumps Respiratory Supplies

Diaphragms IUDs Syringes

Elastic Braces IV Tubing Thermometers
Enteral Nutrition Supplies IV Sets Vaporizers

A drug product must have an NDC, UPC, or HRI with packaging and ingredient information from the manufacturer/distributor to be added to MED-File v2.

MED-File v2 includes all active items in Wolters Kluwer Clinical Drug Information's internal database as well as information for recently discontinued drug products (up to 48 months from the date the item became inactive).

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#### Source of Information

The information Wolters Kluwer Clinical Drug Information uses within MED-File v2 is obtained and/or derived from information provided to Wolters Kluwer Clinical Drug Information by drug manufacturers.

The information contained in MED-File v2 consists of drug product names, current pricing, ingredients, and associated drug product descriptors. Selected fields are discussed in detail on the following pages. Information on other fields is available upon request.

## **Proprietary Drug Concepts**

MED-File v2 contains various drug concepts that are proprietary to Wolters Kluwer Clinical Drug Information. These concepts are listed below:

- Drug Name
- Dose Form Drug
- Drug Descriptor Identifier (DDID)
  - > This concept is also referred to as Dispensable Drug
- Generic Product Identifier (GPI)
- Generic Product Packaging Code (GPPC)
- Routed Dose Form Drug
- Routed Drug

The name-based drug concepts (Drug Name, Dose Form Drug, Routed Drug, Routed Dose Form Drug, and Drug Descriptor Identifier) are based on unique drug trade (brand) names and generic names. These concepts differ in their level of specificity. The functions being performed determine the level of namebased concept that is required.

For more information about using these name-based drug concepts, go to Chapter 5: Applications.

#### **Drug Name**

A Drug Name displays the product name shown by the manufacturer on the package. See below for more information regarding the Drug Name:

- The Drug Name has a maximum of 30 characters and is presented in mixed case.
- For each drug product in the Wolters Kluwer Clinical Drug Information database, there is a generic name and a brand name. Even if a drug is not yet marketed in generic form, a generically-based Drug Name is provided. This generic-based name is derived from the Drug Name and

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- Drug Name Extension (first 10 characters of the Generic Product Identifier), but has a limit of 30 characters.
- When the product name exceeds 30 characters, Wolters Kluwer Clinical Drug Information's editorial policy guides how the name is modified to fit in the allotted space. For example, if the dosage form is part of the name, it may be removed. This is especially common with multiple ingredient cough and cold combinations.
- The Drug Name does not include flavors, colors, shapes, repacks, packaging, or other attributes that a manufacturer may include.
  - > Exception: Oral contraceptives, such as Ortho-Novum 7/7/7 (28)
- Abbreviations are used only when necessary for space and are restricted to common abbreviations.
- The Drug Name does not include dosage form information unless excluding that information results in a nonsensical name (for example, Baby Oil).
- The Drug Name does not include strength(s) unless the strength is actually part of the product name. For example, Acetaminophen-Codeine #2.
- The Drug Name does not include symbols (for example, slashes, dashes, w/, or &) for Brand or Branded Generic names unless represented in the product name by the manufacturer.
- The generic product name includes a hyphen to separate multiple active ingredients, when present.

#### Tall Man Letters

Wolters Kluwer Clinical Drug Information includes Tall Man letters to distinguish similar drug names and reduce the potential for medication errors. Tall Man drug letters identified by the following sources are included:

- United States Food and Drug Administration (FDA)
- Institute for Safe Medication Practices (ISMP)

FDA and ISMP are the only sources for Tall Man letters. If the manufacturer has labeled its product with upper and lower case letters that are not recognized as Tall Man by ISMP, they will be included in the Drug Name only if the product name is a Trademarked or Branded Generic product. Generically-named products will follow normal naming policies with the first letter of the generic name in upper case and the remainder of the name in lower case. Only Tall Man letters defined by the FDA or ISMP will be retained when Wolters Kluwer Clinical Drug Information creates all upper case brand names, all lower case generic names, and salt names that are provided in the Description File.

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#### Note

Tall Man letters provided by Wolters Kluwer Clinical Drug Information should be maintained in your application and presented in all instances, whether in a visual display or a hard copy report. An example of drug names with Tall Man letters are VinCRIStine Sulfate and VinBLAStine Sulfate.

#### Examples:

The table below provides examples with a "Drug Name" Concept Type:

Drug Name
Artificial Tears
VinCRIStine Sulfate
Diltiazem HCI CR
Vytorin
HalfLytely Bowel Prep

#### **Dose Form Drug**

A Dose Form Drug represents the Drug Name and a Dosage Form. The unique combination of Drug Name and Dosage Form is assigned a 10-digit Concept ID.

The same Drug Name may be associated with one or many Dose Form Drugs. The same Dosage Form may be associated with one or many Dose Form Drugs.

#### Note

The Dosage Form value should be translated to its Full Textual Description as defined in the Description File. Use of the Abbreviated Textual Description is discouraged. Significant patient safety issues are related to the use of non-standard abbreviations such as those found in the Dose Form ID and its corresponding Abbreviated Textual Descriptions.

#### Examples:

The table below provides examples with a "Dose Form Drug" Concept Type:

Dose Form Drug
Artificial Tears Ointment
VinCRIStine Sulfate Solution
Diltiazem HCI CR Capsule Extended Release 12 Hour
Vytorin Tablet
HalfLytely Bowel Prep Kit

#### **Routed Drug**

A Routed Drug represents the Drug Name and a Route. The unique combination of Drug Name and Route are assigned a 10-digit Concept ID.

The same Drug Name may be associated with one or many Routed Drugs.

#### Note

The Route value should be translated to its Full Textual Description as defined in the Description File. Use of the Abbreviated Textual Description is discouraged. Significant patient safety issues are related to the use of non-standard abbreviations such as those found in the Route ID and its corresponding Abbreviated Textual Description.

#### Examples:

The table below provides examples with a "Routed Drug" Concept Type:

Routed Drug
Artificial Tears Ophthalmic
VinCRIStine Sulfate Intravenous
Diltiazem HCI CR Oral
Vytorin Oral
HalfLytely Bowel Prep Oral

#### **Routed Dose Form Drug**

A Routed Dose Form Drug represents the Drug Name, Route, and Dosage Form. The unique combination of Drug Name, Route, and Dosage From are assigned a 10-digit Concept ID.

The same Routed Drug may be associated with one or many Routed Dose Form Drugs. The same Route may be associated with one or many Routed Dose Form Drugs. The same Dose Form may be associated with one or many Routed Dose Form Drugs.

#### Note

The Route and Dosage Form values should be translated to their Full Textual Description as defined in the Description File. Use of the Abbreviated Textual Description is discouraged. Significant patient safety issues are related to the use of non-standard abbreviations such as those found in the Route ID and Dose Form ID and their corresponding Abbreviated Textual Descriptions.

#### Examples:

2-6 MED-File v2 Published: 11/11 Revised: 04/18 The table below provides examples with a "Routed Dose Form Drug" Concept Type:

Routed Dose Form Drug
Artificial Tears Ophthalmic Ointment
VinCRIStine Sulfate Intravenous Solution
Diltiazem HCI CR Oral Capsule Extended Release 12 Hour
Vytorin Oral Tablet
HalfLytely Bowel Prep Oral Kit

#### **Drug Descriptor Identifier**

The Drug Descriptor Identifier (DDID) identifies a unique combination of Drug Name, Route of Administration, Dosage Form, Strength, and Strength Unit of Measure. The DDID is used to identify a unique drug product with respect to these fields alone and does not distinguish between marketed drug products based on the size of their respective packages, prescription or over-the-counter status, bioequivalence codes, or other factors.

#### **DDID Unique Combinations**

The Same	May be Associated with
Routed Drug, Dose Form Drug, or	one or many DDIDs
Routed Dose From Drug	
Route	one or many DDIDs
Dose Form	one or many DDIDs

### Note

In the Drug Name File, the DDID is defined as a six-digit number. In the Dispensable Drug File, the DDID is defined as a 10-digit number. They represent the same drug concept. For example, the DDID of "000232" in the Drug Name file and the Concept ID of "0000000232" in the Dispensable Drug File both identify "Accupril Oral Tablet 10 MG".

The New Drug Descriptor Identifier field in the Drug Name file allows tracking of changes to the Drug Descriptor Identifier by linking the old and new DDIDs.

Sources of DDID changes include

- Product/Manufacturer
- United States Pharmacopeia (USP) and FDA
- Customer feedback
- Clerical errors

DDID changes can occur in any on of the five fields. Depending on the type of change that occurs, the existing DDID may be updated or a new DDID may be created.

For more information on the DDID, see below:

- When the Drug Name is changed and a new Drug Name is created, the following applies:
  - > If the change results in a one-to-one replacement, and the DDIDs remain the same clinically, the old and new DDIDs are linked.
  - > If one DDID is split into multiple new DDIDs, the old and new DDIDs are not linked.
- When the Drug Name is changed and the existing DDID is changed, the following applies:
  - > The DDID remains the same clinically.
  - Changes occur for spelling errors, spacing, abbreviations, or special characters such as hyphens, additional information added to the Drug Name, or casing of letters in the drug name, including those from the manufacturer and from ISMP Tall Man letters.
- When the Route is changed, a new DDID is assigned.
  - > If the change results in a one-to-one replacement, and the DDIDs remain the same clinically, the old and new DDIDs are linked.
  - > If a one-to-many replacement is made, the old and new DDIDs are not linked.
- When the Dosage Form is changed, a new DDID is assigned.
  - > If the change results in a one-to-one replacement, and the DDIDs remain the same clinically, the old and new DDIDs are linked.
  - > If a one-to-many replacement is made, the old and new DDIDs are not linked.
- When the Strength and/or Strength Unit of Measure are changed, a new DDID is assigned, the following applies:
  - > If a completely new Strength and/or Strength Unit of Measure results, there is a one-to-one replacement, and the DDIDs are clinically the same, the old and new DDIDs are linked.
  - > If a one-to-many replacement is made, the old and new DDIDs are not linked.
  - > If the DDIDs are not clinically the same, the old and new DDIDs are not linked.
- When the Strength and/or Strength Unit of Measure are changed resulting in changes to the existing DDID, the following applies:
  - > Changes occur to correct the order of strengths in multiple ingredient products, spacing, abbreviations, special characters, or to add additional information.

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#### **Examples:**

The table below provides examples of the DDID as presented in the Drug Name File and in the Description file for those data with a "Dispensable Drug" Concept Type.

Drug Name	Route	Dosage Form	Strength	Strength Unit of Measure
Artificial Tears	Ophthalmic	Ointment		
VinCRIStine Sulfate	Intravenous	Solution	1	MG/ML
Diltiazem HCI CR	Oral	Capsule Extended Release 12 Hour	120	MG
Vytorin	Oral	Tablet	10-10	MG
HalfLytely Bowel Prep	Oral	Kit	5-210	MG-GM

#### Alternatives for Drug Name and for Strength and Strength Unit of Measure

MED-File v2 includes the below descriptions in the Description File in addition to the full text description for Drug Name, Dose Form, Route, and for Strength and Strength Unit of Measure:

- Abbreviated textual description
- Capitalized Name
- Salt Name
- Alternate Name

These names provide options in your application to meet the needs of your endusers.

Below are listed a few examples you may wish to include:

- All UPPER CASE brand name, in place of a mixed case name
- All lower case generic name, in place of a mixed case name
- Strength and its associated Strength Unit of Measure grouped together for a multiple ingredient product

Note

When a Drug Name includes Tall Man letters per FDA and/or ISMP, these letters are maintained. In this case, an all UPPER CASE brand name or an all lower case generic name is not provided; however, Tall Man letters defined only by the manufacturer will not be retained when Wolters Kluwer Clinical Drug Information creates all upper case brand names, all lower case generic names, and salt names that are provided in the Description File.

Abbreviated textual descriptions enable you to associate the Routes and Dosage Forms in the Validation/Translation File to those in the Description File, and the files that use the Description File.

Note	Abbreviated Routes and Dose Forms are provided for use by developers. The
	abbreviated format is not intended for display or print in end-user
	applications.

Salt names represent the base ingredient, and are provided in lower case. They exclude the salt unless it is integral to differentiating one ingredient from another. For example, hydrocortisone acetate vs. hydrocortisone valerate.

Alternate names are provided for Dose Forms and for Strength/Strength Unit of Measure representations.

The table below illustrates Drug Name, Strength/Strength Unit of Measure, and Dose Form descriptions that are available in MED-File v2.

#### Examples:

Concept Type	Description Type	Description	
Drug Name	Full textual description	FIUoxetine HCI	
	Salt name	FIUoxetine	
Drug Name	Full textual description	Atorvastatin Calcium	
	Salt name	atorvastatin	
Drug Name	Full textual description	Calcium Carbonate	
	Salt name	calcium carbonate	
Drug Name	Full textual description	Crestor	
	Capitalized name	CRESTOR	
Strength & Strength Unit of	Full textual description	1000-4-60 MG	
Measure	Alternate name	1,000 mg - 4 mg - 60 mg	
Dose Form	Full textual description	Tablet Chewable	
	Abbreviated textual	CHEW	
	description		
	Alternate name	Chewable Tablet	

#### **Generic Product Identifier**

Wolters Kluwer Clinical Drug Information's Generic Product Identifier (GPI) defines pharmaceutically equivalent drug products that are identical in terms of:

- active ingredient(s)
- route of administration

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- dosage form
- strength or concentration
- therapeutic use

Clinical considerations may also enter into the GPI assignment. The GPI does not consider the following:

- manufacturing process
- patent or intellectual property rights
- differences in bioequivalence or therapeutic equivalence
- inactive ingredients
- legal restrictions for substitution

The GPI categorizes drug products by a hierarchical therapeutic classification scheme for use in the following:

- formulary management
- market research
- various reporting applications

The unique and proprietary therapeutic basis of this system is more useful than conventional pharmacological approaches to drug classification. This coding system is based on subsets contained in the GPI structure. Drug product records containing a GPI may be readily manipulated to categorize drug products at various levels of specificity.

A common application and use of Wolters Kluwer Clinical Drug Information's data is the identification of generic and therapeutic equivalents. Different markets and applications have different definitions of a generic drug product. The GPI is considered a starting point for selecting generic drug products and must be used in conjunction with other data elements for drug product identification. An example is the FDA's Orange Book Therapeutic Equivalence Evaluation Code (refer to the section entitled "Generic Substitution Versus Therapeutic Alternate Identification").

#### Note

Drug products identified as "pharmaceutical equivalents" are not necessarily bioequivalent or therapeutically equivalent. Differences in bioequivalence and legal restrictions concerning drug product substitution may result from brand interchange or drug product substitution.

Dosage forms considered within the GPI hierarchy are based on Wolters Kluwer Clinical Drug Information's proprietary dosage form concept.

In assigning the GPI, Wolters Kluwer Clinical Drug Information considers the therapeutic use of the drug. In some instances, drugs may be classified in a

common therapeutic area for ease of identification and selection (see also Multiple Indications).

#### Wolters Kluwer Clinical Drug Information's Therapeutic Classification System (TCS)

The first 10 characters of the GPI identify the drug product according to Wolters Kluwer Clinical Drug Information's Therapeutic Classification System (TCS). For more information regarding Wolters Kluwer Clinical Drug Information's TCS, see Appendix E, "Wolters Kluwer Clinical Drug Information's Therapeutic Classification System".

#### **GPI Structure**

The 14-character GPI consists of seven subsets, each providing increasingly more specific information about drug products. Asterisks included in the drug product name refer to the position of the product within Wolters Kluwer Clinical Drug Information's TCS. The asterisk before the name indicates the location is within the first three Record Types; the asterisk(s) after the name indicates the level of specificity. Record Types 1 through 3 will always contain asterisks; Record Type 5 will only contain asterisks for partial GPIs. (Refer to Partial GPI Codes later in this chapter for more information.) These subsets are structured and identified below:

Subset	Record Type	Number of Characters	Description	Example
12-xx-xx-xx-xx-	1	2	Drug Group	ENDOCRINE AND METABOLIC AGENTS - MISC.*
12-34-xx-xx-xx-	2	4	Drug Class	*Posterior Pituitary Hormones***
12-34-56-xx-xx-xx-	3	6	Drug Subclass	*Vasopressin***
12-34-56-78-xx-xx-	6	8	Drug Base Name	Desmopressin
12-34-56-78-90-xx-xx	4	10	Drug Name/Drug Name Extension	Desmopressin Acetate
12-34-56-78-90-12-xx	7	12	Drug Name and Dosage Form	Desmopressin Acetate Tablet
12-34-56-78-90-12-34	5	14	Full GPI with Drug Strength and Strength	Desmopressin Acetate Tablet 0.1 MG

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#### **Subsets**

#### **Drug Group**

The two-character Drug Group (first subset) classifies general drug products. These 99 Drug Groups include the Drug Classes frequently used in general market research and third-party prescription processing.

#### Examples include:

01	*PENICILLINS*
25	*CONTRACEPTIVES*
27	*ANTIDIABETICS*
36	*ANTIHYPERTENSIVES*
86	*OPHTHALMIC AGENTS*

#### **Drug Class**

The four-character Drug Class (first and second subset) identifies specific therapeutic drug classes designed to accommodate more detailed market research. The Drug Class also serves as the structural base for most therapeutic drug monitoring applications (such as dosage screening and disease contraindication monitoring). For example, Drug Group 37, DIURETICS, includes the following Drug Classes:

37	*DIURETICS*
37-10	*Carbonic Anhydrase Inhibitors**
37-20	*Loop Diuretics**
37-30	*Mercurial Diuretics**
37-40	*Osmotic Diuretics**
37-50	*Potassium Sparing Diuretics**
37-60	*Thiazides and Thiazide-Like Diuretics**
37-90	*Diuretics-Miscellaneous**
37-99	*Diuretic Combinations**
Note	"99" in the second or third subset is used to identify multiple ingredient (combination) drug products.

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#### **Drug Subclass**

The six-character Drug Subclass (first through third subset) is used if further distinction is needed within a Drug Class. For example, the Drug Class 21-40, Antineoplastic - Hormonal Agents, includes the following Drug Subclasses:

#### 21 \*ANTINEOPLASTICS AND ADJUNCTIVE THERAPIES\*

21-40	*Antineoplastic - Hormonal and Related Agents**
21-40-20	*Androgens - Antineoplastic***
21-40-22	*Antiadrenals***
21-40-24	*Antiandrogens***
21-40-26	*Antiestrogens***
21-40-28	*Aromatase Inhibitors***
21-40-30	*Estrogens - Antineoplastic***
21-40-35	*Estrogen Receptor Antagonist***
21-40-40	*Progestins - Antineoplastic***
21-40-50	*LHRH Analogs***
21-40-55	*Gonadotropin Releasing Hormone (GnRH) Antagonists***
21-40-60	*Androgen Biosynthesis Inhibitors***

#### **Drug Base Name**

The eight-character Drug Base Name (first through fourth subset) designates the basic drug moiety. The Drug Base Name may represent the therapeutic class and not a specific moiety. This often occurs with combination products. For example, the Drug Subclass 30-04-20, Bisphosphonates, includes the following Drug Base Names:

30-04-20	Bisphosphonates***
30-04-20-10	Alendronate
30-04-20-40	Etidronate
30-04-20-48	Ibandronate
30-04-20-60	Pamidronate
30-04-20-65	Risedronate
30-04-20-70	Tiludronate
30-04-20-90	Zoledronic Acid

#### Drug Name and Drug Name Extension

The 10-character Drug Name and Drug Name Extension (first through fifth subset) designates the specific drug and salt, when applicable. When no salt is

2-14 MED-File v2 Published: 11/11 Revised: 04/18 present, the Drug Name and Drug Name Extension will be the same as the Drug Base Name. For example, Drug Base Name 22-10-00-20, Dexamethasone, includes the following Drug Names and Drug Name Extensions:

22-10-00-20-	Dexamethasone
22-10-00-20-10	Dexamethasone Acetate
22-10-00-20-20	Dexamethasone Sodium Phosphate

For combination drug products, the fourth subset generally specifies the number of active ingredient(s) in a multiple ingredient (combination) product. The fifth subset designates the specific combination of ingredients in the drug product. For example, Drug Subclass 43-99-30, Decongestant & Antihistamines, includes, but is not limited to, the following combination drug products:

43-99-30	*Decongestant & Antihistamine***
43-99-30-02-03	Acrivastine & Pseudoephedrine
43-99-30-02-05	Astemizole & Pseudoephedrine
43-99-30-02-10	Azatadine & Pseudoephedrine
43-99-30-02-25	Carbinoxamine & Phenylephrine
43-99-30-02-30	Chlorpheniramine & Phenylephrine
43-99-30-02-59	Loratadine & Pseudoephedrine
43-99-30-02-70	Promethazine & Phenylephrine
43-99-30-02-72	Promethazine & Pseudoephedrine
43-99-30-02-80	Triprolidine & Pseudoephedrine
43-99-30-03-05	Brompheniramine-Diphenhydramine-Phenylephrine
43-99-30-03-24	Chlorpheniramine-Pyrilamine & Phenylephrine

#### **Drug Name and Dosage Form**

The 12-character Drug Name and Dosage Form (first through sixth subsets) designates the specific drug and its dosage form. For example, Drug Name and Drug Name Extension 67-40-60-70-10, Sumatriptan Succinate, includes the following Drug Name and Dosage Forms:

67-40-60-70-10	Sumatriptan Succinate
67-40-60-70-10-03	Sumatriptan Succinate Tablet
67-40-60-70-10-20	Sumatriptan Succinate Solution
67-40-60-70-10-62	Sumatriptan Succinate Device
67-40-60-70-10-64	Sumatriptan Succinate Kit

#### Full GPI with Drug Strength and Strength UOM

The 13th and 14th characters (seventh subset) identify various strengths. For example, Drug Name and Dosage Form 37-20-00-30-00, Furosemide, includes the following:

37-20-00-30-00-03	Furosemide Tablet
37-20-00-30-00-03-05	Furosemide Tab 20 MG
37-20-00-30-00-03-10	Furosemide Tab 40 MG
37-20-00-30-00-03-15	Furosemide Tab 80 MG
37-20-00-30-00-20-05	Furosemide Inj 10 MG/ML
37-20-00-30-00-20-50	Furosemide Oral Soln 10 MG/ML

Note	The seventh subset can also imply a route when the first twelve characters
	of the GPI cannot define the route difference, as illustrated by the last two
	rows in the table above.

When strengths are not specified, the seventh subset may be "00". For example, Drug Name 90-55-00-75, Hydrocortisone, includes the following dosage forms without strengths:

90-55-00-75-00-29-00	Hydrocortisone Powder
90-55-00-75-10-29-00	Hydrocortisone Acetate Powder

#### **GPI Change Policy**

Once assigned to a drug product, a GPI generally does not change for an NDC-UPC-HRI; however, it may be reassigned for one of the following reasons:

- alteration of Wolters Kluwer Clinical Drug Information's TCS to maintain integrity and usefulness of this system
- refinement of dosage form or strength designations for an ingredient
- · error correction to the original GPI assignment

Note	Wolters Kluwer Clinical Drug Information will provide developers and end- users with advance notice for GPI revisions due to the first two reasons
	above; however, error corrections are made without advance notice. GPI
	Error corrections are published in weekly DataFacts. Contact Customer
	Support for more information regarding DataFacts.

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#### **Multiple Indications**

Drug products that typically have common, yet diverse, therapeutic uses are often classified by pharmacological class. For example, Propranolol is found under Beta-blockers. Beta-blockers are grouped with other cardiovascular drugs because the cardiovascular uses of Beta-blockers are more common than possible therapeutic uses (such as for migraine headaches). Occasionally, multiple GPIs are assigned to an active ingredient. This usually occurs when drug products are packaged and marketed for specific indications. For example, Diphenydramine is found under Antihistamines – Ethanolamines and also under Antihistamine Hypnotics.

#### Partial GPI Codes

Only drug products identified with identical 14-character GPIs are pharmaceutically equivalent. A partial GPI refers to a general description of the product based on Wolters Kluwer Clinical Drug Information's TCS. For example, multiple vitamin products are identified by therapeutic class name as illustrated below:

47-30-00-25-00-01-00	*Probiotic Product - Cap**
78-12-00-00-00-03-00	*B-Complex w/C Tab**
80-50-00-30-00-01-90	*Omega-3 Fatty Acids Cap 1000 MG**

Note

Partial GPIs are identified and differentiated from specific GPIs by asterisks before and after the GPI name. Drug products having identical Partial GPIs are not pharmaceutically equivalent drug products.

#### Generic Substitution Versus Therapeutic Alternate Identification

MED-File v2 may be used to aid in determining generic and therapeutic equivalents.

Generic substitution involves identifying pharmaceutically equivalent drug products substituted for the originator/trademarked drug products. Pharmaceutically equivalent drug products contain the same active ingredient(s), dosage form, route, and strength or concentration. The GPI can be used to determine pharmaceutical equivalents.

Therapeutic Alternate Identification involves substituting a therapeutically similar drug product for the prescribed drug product. Therapeutic alternates may originate from the same general Drug Grouping (Anti-infective Agents), Drug Group (Cephalosporins), or Drug Class (Cephalosporins - Second Generation). The structure of Wolters Kluwer Clinical Drug Information's GPI and

TCS helps determine different therapeutic equivalents or alternates depending on the number of GPI characters matched.

#### Generic Substitution

Drug products identified as pharmaceutically equivalent are not necessarily bioequivalent (drug products entering the patient's bloodstream at the same rate and in the same amount as the originator drug product) or therapeutically equivalent. Once pharmaceutically equivalent drug products are identified, further restrictions may be necessary to identify generic substitutable alternates for different markets and end-users. Differences in bioequivalence and legal restrictions concerning drug product substitution may result from brand interchange or product substitution. (Refer to the Therapeutic Equivalence Evaluation (TEE) Codes for more information on bioequivalency.)

The following can be used to determine generic substitutable drug products: GPIs, "Generic" drug products, and TEE Codes.

#### Generic Product Identifier (GPI)

The GPI identifies pharmaceutically equivalent drug products that are identical in active ingredient(s), dosage form, route, and strength or concentration. Different markets and applications have different definitions of a generic drug product. The GPI is a starting point for selecting generic drug products and should be used in conjunction with other data elements for drug product classification. The GPI does not consider the presence of inactive ingredients. Retrieval of NDCs-UPCs-HRIs with exact 14-character GPI matches (that are not partial GPIs) becomes the starting point for selecting "generic" drug products.

#### "Generic" Drug Products

Different markets and applications have different definitions of a "generic" drug product. Wolters Kluwer Clinical Drug Information supplies several codes which, when used with the GPI, determine the following:

- Whether the drug product is available by another source (Multi-Source Code)
- How the drug product is named (Brand Name Code)
- How the Labeler/Manufacturer promotes their drug products (Labeler Type Code)
- Therapeutic Equivalence Evaluation of the drug product (TEE Code)

The Multi-Source Summary Code assigned to a DDID in the Drug Name File is referred to as the Multi-Source Code in the NDC File. The Brand Name Code assigned to a DDID in the Drug Name File is referred to as the Name Type Code in the NDC File.

2-18 MED-File v2 Published: 11/11 Revised: 04/18 For more information, see Chapter 4, "MED-File v2 Data Elements" in this manual for details on each code. The table below illustrates how the codes, used together, can determine the best fit for the end-user's requirements.

Note

The Multi-Source Code is not updated for inactive drug products when generic availability changes. This value is only meaningful in relation to currently marketed (active) drug products.

#### Example:

Drug Products	Multi-Source Code	Brand Name Code	Description		
Trademarked Products	M, N	T	<ul> <li>Generally a tradename drug product</li> <li>One drug product, or colicensed drug products, are available for this GPI</li> <li>Manufactured by a research and development company</li> <li>Sold under a trademarked name</li> </ul>		
Trademarked Products	0	T	<ul> <li>Generally a tradename drug product</li> <li>More than one company manufactures this drug product</li> <li>The manufacturer, usually a research and development company, is the originator of the drug product</li> <li>Usually sold under a trademarked name</li> </ul>		
Branded Generic or Generic Products Based on End-User Requirements	0	B,G	<ul> <li>Generally a generic drug product</li> <li>More than one company manufactures this drug product</li> <li>The Manufacturer can be a research and development company or a generic company</li> <li>Sold under a branded generic or a generic name</li> </ul>		

Drug Products	Multi-Source	Brand Name	Description		
	Code	Code			
Trademarked or Generic Products Based on End- User Requirements	Y	Т	<ul> <li>Generally a tradename drug product</li> <li>More than one company manufactures this drug product</li> <li>The manufacturer is not the originator of the drug product</li> <li>Manufactured by a research and development company</li> <li>Sold under a trademarked name</li> </ul>		
Branded Generic or Generic Products	Y	B, G	<ul> <li>Generally a generic drug product</li> <li>More than one company manufactures this drug product</li> <li>The manufacturer is not the originator of the drug product</li> <li>Manufacturer is generally a generic company</li> <li>Sold under a generic name</li> </ul>		
Generic Products	M, N	G	<ul> <li>Generally a generic drug product</li> <li>Only one company manufactures this drug product</li> <li>Only one drug product is available for this GPI</li> <li>Sold under a generic name</li> </ul>		
Branded Generic Products	M, N	В	<ul> <li>Generally a branded generic drug product</li> <li>Only one company manufactures this drug product</li> <li>Only one drug product is available for this GPI</li> <li>Sold under a generic name</li> </ul>		

Application of these fields varies; apply your own rules to differentiate between generic and brand drug products. Additionally, the price of the drug product may be more significant than brand or generic status.

2-20 MED-File v2 Published: 11/11 Revised: 04/18 Once drug products sharing the same non-partial GPI and the appropriate additional codes values are determined, the TEE Code must then be used to help determine the *substitutability* of the drug products.

#### Therapeutic Equivalence Evaluation (TEE) Codes

When a brand name drug product is prescribed but a generic product is preferred, using the GPI is helpful in determining the alternatives. Retrieval of NDCs-UPCs-HRIs that match all 14 characters of the GPI provides a list of generic alternatives. However, it is often insufficient to select a drug product from a list of NDCs-UPCs-HRIs with matching GPIs. Matching GPIs (not including Partial GPIs) only indicate the same mixture of active ingredients with the same route, strength, and dosage form. A determination of which drug products are bioequivalent is needed. Use of the TEE Code will indicate which drug products are bioequivalent. This is the true measure of drug product activity when considering which drug products are suitable for generic substitution. TEE Codes beginning with "A" (except for TEE Codes "A1" and "A2") represent bioequivalent drug products according to the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book). Using the TEE Code with the GPI enables the end-user to have a list of substitutable drug products sharing the same active ingredients including the same route, strength, and dosage form.

#### **Generic Product Packaging Code**

The Generic Product Packaging Code (GPPC) generically defines a drug product and its packaging similar to how the GPI defines the generic ingredient and therapeutic use.

The GPPC is an eight-character code. The first five characters of the GPPC are random and represent a GPI (GPPC-Core). The last three characters contain the GPPC-Suffix and represent the Package Description, Package Size, Package Size Unit of Measure, Package Quantity, and Unit-Dose/Unit-of-Use Package Code.

The linking of drug products with the same GPPC-Core identifies all drug products with the same GPI which includes generic ingredient, strength, and dosage form. The GPPC-Suffix is alphanumeric to allow for the large number of packaging variations. The GPPC-Suffix represents the same information regardless of the associated GPPC-Core (for example, GPPC-Suffix "003" always

represents bottles of 100 eaches, tablets, capsules, etc.). The table below illustrates the structure of the GPPC.

Description	GPPC	
	Core	Suffix
Valium, Tabs, 5 mg, Bottle, 100s ea.	02974	003
Diazepam, Tabs, 5 mg, Bottle, 100s ea.	02974	003
Diazepam, Tabs, 5 mg, Bottle, 500s ea.	02974	027
Diazepam, Tabs, 5 mg, Unit Dose, 100s ea.	02974	028
Diazepam, Inj., 5 mg/ml, Amp, 2 ml, 50s ea.	02978	A04
Acetaminophen w/Codeine, Caps, 30 mg, Bottle, 100s ea.	03634	003

Drug products identified by a Partial GPI are also assigned a GPPC. However, these drug products have the same limitations as Partial GPI Codes.

The fields defining the GPPC are available in the data elements noted previously. The GPPC can be applied in various ways depending on the practice setting. For example:

- manufacturers can identify comparable drug products from competitors for price comparisons and decisions
- wholesalers can use the data to manage purchasing decisions, control inventory, and reduce overlap between similar drug products from different generic companies
- hospitals can track product use, provide more accurate estimations in bid order purchasing, and reduce or eliminate overlap of same drug products in the formulary
- Third-Party Administrators (TPAs) can control costs by setting a range for reimbursement limits of like GPPCs and investigating those claims falling outside the range
- Pharmacies can use the data to improve purchasing decisions between generic companies and better manage their inventory

### **External Drug Concepts**

#### NDC-UPC-HRI

NDCs and HRIs are 10- or 11-character codes used to identify drug products. Non-prescription drug products may also have a separate UPC according to the standards set forth by the GS1. These codes are converted to eleven characters according to the National Council on Prescription Drugs Program (NCPDP) standards.

2-22 MED-File v2 Published: 11/11 Revised: 04/18 Generally, the 11-character NDC is divided into three sections:

- The first five digits indicate the manufacturer
- The next four digits indicate the drug product
- The last two digits indicate the packaging.

**Note** There are instances where a manufacturer/distributor will use the same first nine characters to indicate two distinct drug products. This limitation should be considered in your implementation.

The first four or five characters of the NDC or HRI (depending on the format) are assigned by the Food and Drug Administration (FDA) Drug Listing Branch to identify manufacturers. This is the same as the Medi-Span Labeler Identifier, in most cases. The last five or six characters are assigned by manufacturers to identify their product and package designations.

Drug products regulated by the FDA must use an NDC. Companies that are assigned a four-character labeler code use a 4-4-2 format for their drug products; those who have been assigned a five-character labeler code use either the 5-3-2, 5-4-1, or 5-4-2 format. NDCs in the 5-4-2 format do not follow standard formatting rules and do not convert to a 10-character format.

Surgical supplies and non-prescription drug products may have an NDC and an HRI or UPC.

NDCs-UPCs-HRIs that are repackaged are identified in the NDC File of MED-File v2 by the Repackage Code. Institutional packages are additionally identified by a Modifier Code in the NDC Modifier File.

### **ID Number Format Code**

In order to assist developers with converting NDCs-UPCs-HRIs, Wolters Kluwer Clinical Drug Information provides an ID Number Format Code. This code enables the developer to

- determine where to place dashes when formatting for display
- convert from the 10- to 11-character format
- convert from the 11- to 10-character format

### Example:

ID Number Format Code	Represents	ID Type
1	4-4-2	NDC
2	5-3-2	NDC

ID Number Format Code	Represents	ID Type
3	5-4-1	NDC
4	4-6	HRI
5	5-5	UPC
6	5-4-2	NDC

Below are examples illustrating the conversion of NDCs-UPCs-HRIs:

NDC	NCPDP Standard 11-character NDC	11-digit NDC (with hyphens)	ID Format Code
4-4-2 (9999-9999-99)	5-4-2 (0999999999)	09999-9999-99	1
5-3-2 (99999-999-99)	5-4-2 (99999099999)	99999-0999-99	2
5-4-1 (99999-9999-9)	5-4-2 (9999999999)	99999-9999-09	3
5-4-2 (99999-9999-99)	5-4-2 (9999999999)	99999-9999-99	6

UPC or HRI	11-character UPC or HRI	UPC or HRI (with hyphens)	ID Format Code
4-6 (9999-999999)	5-6 (0999999999)	9999-999999	4
5-5 (99999-99999)	5-6 (9999909999)	99999-99999	5

### Changes to an NDC-UPC-HRI

In the case where an NDC-UPC-HRI has changed for a drug product, two records will be output at the time of the change. The old NDC-UPC-HRI record will be output with an item status of "inactive" and the new NDC-UPC-HRI will be provided for reference. The new NDC-UPC-HRI record will be output with an item status of "active" and the old NDC-UPC-HRI will be provided for reference.

### Secondary Alternate Drug IDs

In cases where a drug product may have more than one ID, MED-File v2 includes secondary IDs for a packaged drug and links them together in the Secondary Alternate ID File. For example, a drug may have both an NDC and a UPC. In some instances, the values for the IDs may be the same; however, the ID Format Codes may be different. Currently, only NDCs-UPCs-HRIs are defined as secondary alternate IDs. Additional ID types may be used in the future.

Note	In the Secondary Alternate ID File, the NDC-UPC-HRI values are named
	either the External Drug ID or the Alternate Drug ID. In addition, these fields
	are 20 characters in length to allow for potential future expansion of the
	NDC-UPC-HRI.

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# Ingredients

MED-File v2 includes both active and inactive ingredients for drugs. Inactive ingredients are generally limited to those that are considered clinically significant, although other inactive ingredients may also be included. Examples of clinically significant inactive ingredients include alcohol and tartrazine due to their potential to elicit drug interactions or an allergic reaction, respectively.

Effective March 1, 2018, Medi-Span will report only active ingredients for compounded products from outsourcing facilities. All inactive ingredients will be excluded. Users of products manufactured by outsourcing facilities should understand that comprehensive allergy screening and alerting for allergenic inactive ingredients will NOT occur.

The following information describes some of the ingredient concepts and their relationship to drug products within MED-File v2.

### **Knowledge Base Drug Code**

The Knowledge Base Drug Code (KDC) is a proprietary Wolters Kluwer Clinical Drug Information concept that defines a drug in terms of its ingredients. Single ingredient drugs (for example, acetaminophen) are assigned a KDC. Multiple ingredient drugs (for example, acetaminophen + hydrocodone) are assigned a KDC that represents the ingredient combination.

The KDC is used by some of Wolters Kluwer Clinical Drug Information's clinical databases, including drug-drug interaction and drug allergy screening.

The KDC is 3-part code that is defined as follows:

- The first five digits represent a single ingredient or combination of ingredients. It is often referred to as the drug "moiety". For example, "00068" represents Amoxicillin.
- The first seven digits represent the additional ingredient or ingredients (often a salt) that define the specific alternative form of the drug moiety. For example, "0006801" represents Amoxicillin Trihydrate.
- In cases where there are no salt forms for an ingredient, the five-digit and seven-digit values will have the same description. For example, "00231" and "0023101" both represent Carbamazepine.
- The full 10-digit KDC further distinguishes between products with unique characteristics. It is most often used to identify trade (brand) names associated to the ingredients represented by the KDC. For example, "0006801001" represents Amoxil.

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Note The KDC is not a hierarchical value and the code itself has no meaning
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MED-File includes the full 10-digit KDC as an attribute of the DDID and the NDC-UPC-HRI. The seven-digit KDC is included in the Ingredient Drug File where it can be associated to an ingredient name.

### **Association of Ingredients to Drug Concepts**

### Ingredient Set

The Ingredient Set is a proprietary Wolters Kluwer Clinical Drug Information concept that uniquely defines the collection of one or more active and significant inactive ingredients of a product formulation.

### Ingredient Name

Each ingredient in the Wolters Kluwer Clinical Drug Information database is assigned a name based on the United States Adopted Name (USAN). When the USAN name is not available, the name reflects the name used by the Chemical Abstracts Service (CAS) or other sources such as the manufacturer, if these names are not available.

### Ingredient Strength and Strength Unit of Measure

The strength and strength unit of measure for an ingredient are represented as follows:

- The ingredient strength is a numeric value representing the metric strength, when available. This value may indicate a ratio strength or percentage.
- The strength unit of measure represents the units for the ingredient strength. It can be a percentage or part of a ratio strength.

### Examples:

Drug	Ingredient	Ingredient Strength	Ingredient
			Strength UOM
DDID 47942	ATORVASTATIN	10	MG
Lipitor Oral	CALCIUM		
Tablet 10 MG			
DDID 88732	SIMVASTATIN	10	MG
Vytorin Oral Tablet 10-10 MG	EZETIMIBE	10	MG

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Drug	Ingredient	Ingredient Strength	Ingredient Strength UOM
DDID 282 Acetaminophen Oral Solution 160 MG/5 ML	ACETAMINOPHEN	160	MG/5ML
DDID 3949 Carmol 10 External Lotion 10%	UREA (CARBAMIDE)	10	%
NDC 00904-3233-	CHOLECALCIFEROL	400	UNIT
52 Calcium Carbonate-	CALCIUM CARBONATE	600	MG
Vitamin D 600- 500 MG-UNIT	FD&C YELLOW #6 (SUNSET YELLOW)		

### Representative Ingredient Set

When more than one set of ingredients exists for a drug concept, a representative ingredient set may be assigned. This is especially common for a DDID that represents more than one NDC-UPC-HRI. The formulations of the drug product by different manufacturer may vary, especially with respect to inactive ingredients. The following guidelines are followed:

- For a generically-named DDID, the representative ingredient set is based on the active ingredients only. Inactive ingredients are not considered.
- For a brand name DDID, the active and inactive ingredients are considered. If more than one ingredient set is possible, the representative ingredient set is the most recently created ingredient set.
- If the DDID is associated with a partial GPI that is not specific to all ingredients, no representative ingredient set is assigned.

### Example:

Drug Concept & Description	Ingredient Set	Ingredient	Ingredient Strength & Strength UOM
DDID 913 ALPRAZolam Oral Tablet 0.25 MG	1341	ALPRAZOLAM	0.25 MG
NDC 00228-2027- 10 ALPRAZolam Oral Tablet 0.25 MG	1341	ALPRAZOLAM	0.25 MG
NDC 00603-2127-	64871	ALPRAZOLAM	0.25 MG
21 ALPRAZolam Oral Tablet 0.25 MG		SODIUM BENZOATE	

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### Chemical Abstracts Service (CAS) Registry Number

MED-File v2 includes the Chemical Abstracts Service (CAS) Registry Number, when available. This number represents a unique external identifier for chemical substances, enabling the use of a non-proprietary means to identify drug ingredients.

#### Generic ID

Wolters Kluwer Clinical Drug Information provides its proprietary Generic ID concept value for ingredients with and without CAS Registry Numbers.

# **Pricing**

This section describes the types of pricing, the pricing policy, and pricing attributes included in MED-File v2.

Your license agreement will determine whether or not your MED-File v2 Note product includes drug pricing information.

### Average Wholesale Price (AWP)

The Clinical Drug Information, LLC Average Wholesale Price (AWP) is intended only to be used by Clinical Drug Information, LLC customers. While many customers use this information as a price index, the Clinical Drug Information, LLC AWP does not represent an average of wholesale prices from any group of transactions in the marketplace and a wholesaler may agree to sell its products to one or more of its customers at a lower price through the use of any number of methods, such as discounts or rebates.

For a complete explanation of Clinical Drug Information, LLC's AWP Policy, go to http://www.medispan.com/common/pdf/wkh\_AWP\_policy.pdf. You are encouraged to review that AWP Policy carefully and in its entirety, both before using the pricing contained in Wolters Kluwer Clinical Drug Information drug information products and when making ongoing decisions about reasonable and appropriate uses of that information.

As a condition to Clinical Drug Information, LLC publishing the AWP of a product, the manufacturer must supply at least one of the following price types:

- Suggested Wholesale Price (SWP)
- Wholesaler Acquisition Cost (WAC)
- Direct Price (DP)

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In all cases where the manufacturer supplies an SWP, even if accompanied by either or both of a WAC or DP, the AWP value will reflect the manufacturer's SWP as reported to Clinical Drug Information, LLC. In all cases where the manufacturer does not supply an SWP, the AWP results from applying a markup to the manufacturer's reported WAC or DP. DP is only used to determine AWP when the manufacturer does not supply a WAC. The markup applied to the WAC or DP for active products is based either on a standard markup of 20% or from certain historical, wholesaler-reported data where the historical markup is less than 20%.

This AWP pricing policy governs pricing information published in documentation manuals of other Clinical Drug Information, LLC products.

Note

Inactive products prior to September 27, 2009 may have markup factors greater than 20% and were subject to previous Clinical Drug Information, LLC AWP Editorial Policies effective at that time.

### **Direct Price (DP)**

DP represents the price, as reported to Wolters Kluwer Clinical Drug Information by a manufacturer, at which non-wholesalers and providers may purchase drug products from that manufacturer. DP does not necessarily represent the actual sales price in any single transaction, as any manufacturer may sell its products to one or more non-wholesalers or providers at different prices, which, for example, may be reduced as the result of discounts or rebates. Wolters Kluwer Clinical Drug Information generally does not receive a reported DP for drug products that are sold by a manufacturer exclusively through wholesalers, although in some cases both a DP and a WAC may be provided at the manufacturer's discretion.

# Wholesaler Acquisition Cost (WAC)

WAC represents the price, as reported to Wolters Kluwer Clinical Drug Information by a manufacturer, at which wholesalers may purchase drug products from that manufacturer. WAC does not necessarily represent the actual sales price in any single transaction, as any manufacturer may agree to sell its products to one or more wholesalers at a lower price with that wholesaler through the inclusion of any number of methods, such as discounts or rebates.

### Manufacturer's Suggested Wholesale Price (SWP)

SWP is the manufacturer's suggested wholesale price, as reported to Wolters Kluwer Clinical Drug Information by a manufacturer, for its drugs to be sold by wholesalers to their customers. The manufacturer reports this price to Wolters

Documentation Manual 2-29 Published: 11/11 Revised: 04/18 Kluwer Clinical Drug Information. The SWP does not necessarily represent the actual sale price used by a manufacturer in any specific transaction with its own customers. Wholesalers, based on competitive and market factors, determine the actual price they will use to sell the drug product to their customers.

### **AWP Indicator Code**

The AWP Indicator Code is a proprietary Wolters Kluwer Clinical Drug Information concept that indicates how the AWP was obtained by Wolters Kluwer Clinical Drug Information.

The current values are:

Value	Description
Α	Mark-up < 1.20 mfr. WAC or DP
L	Std. mark-up of 1.20 mfr. WAC or DP
S	Mfr. suggested AWP
K	Adj. std. mark-up of 1.20 mfr. WAC or DP
M	Std. mark-up of 1.25 mfr. WAC or DP

#### Note

The codes, descriptions, and definitions above reflect Wolters Kluwer Clinical Drug Information's current AWP editorial policies. This information may have changed over time with announced changes in our AWP editorial policies. Please refer to current and historical editorial polices or contact Wolters Kluwer Clinical Drug Information Customer Support if you have questions regarding use of these codes, descriptions, and definitions.

The AWP Indicator Code is used as follows:

- Prior to September 26, 2009, AWP Indicator Codes of A, S, and M were in
- AWP Indicator Code K was used to make one-time adjustments effective September 26, 2009.
- As of September 27, 2009, AWP Indicator Codes of A, S, and L are used.

# Centers for Medicare and Medicaid Services (CMS) for Federal Upper Limit (FUL) Pricing

MED-File v2 also provides pricing from the Centers for Medicare and Medicaid Services (CMS) for Federal Upper Limit (FUL). This pricing represents the upper price limit established by CMS FUL, when applicable. Data is supplied directly from CMS.

2-30 MED-File v2 Published: 11/11 Revised: 04/18 CMS has developed a list of multiple-source drug products with upper price limits for each specific strength and dosage form. They establish ceiling prices for each set of therapeutically equivalent drug products according to the formula in the Medicaid final regulation published July 31, 1987 by CMS's parent organization, the Department of Health and Human Services (HHS). The rule's aggregate reimbursement ceiling is set at 150% of the lowest published price for therapeutically equivalent multiple-source drug products. CMS periodically updates the list of covered drug products.

# Average AWP (AAWP) and Generic Equivalent Average Price (GEAP)

### **AAWP**

The Average Average Wholesale Price (AAWP) is a proprietary Wolters Kluwer Clinical Drug Information drug pricing concept. Generally, the AAWP represents the average of all AWPs for each multi-source drug product with the same GPPC, not including the originator drug products. This price does not take into consideration the TEE Code assigned to each drug product. When the quantity of manufacturers supplying a generic is insufficient for calculating an average, the AAWP is not calculated. This is a generic price applicable for all drug products sharing the same GPPC; however, all drug products with the same GPPC have not been used in the determination of the AAWP. The AAWP and GEAP Determination section discussed later in this chapter includes the criteria for price determination.

### **GEAP**

The Generic Equivalent Average Price (GEAP) is a proprietary Wolters Kluwer Clinical Drug Information drug pricing concept. Generally, the GEAP represents the average of AWPs for all multi-source drug products with a TEE Code beginning with "A" (therapeutically equivalent), except for those with TEE Code values of "A1" and "A2", in a given GPPC, not including originator drug products. When a drug product has no approved equivalent or the quantity of manufacturers supplying a generic is insufficient for calculating an average, a GEAP is not calculated. The GEAP is a generic price applicable for all drug products sharing the same GPPC; however, all drug products with the same GPPC have not been used in the determination of the GEAP. The AAWP and GEAP Determination section discussed below includes the criteria for price determination.

**Note** GEAPs are not calculated for drug products that have TEE Codes of "A1" or "A2".

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### AAWP and GEAP Determination

The AAWP and GEAP are calculated by Wolters Kluwer Clinical Drug Information and output in the GPPC Price File. The unique key, consisting of the Generic Product Packaging Code, and GPPC Price Code, and Effective Date, is used to identify drug products with the same GPI and packaging used in the calculation. Once drug products meeting the criteria shown below are identified, total the AWPs of the identified drug products and divide by the number of drug products found.

#### Criteria for AAWP Calculation

The following is a list of criteria that must be met in order for Wolters Kluwer Clinical Drug Information to calculate AAWPs:

- There must be at least two drug products coded with "Y" Multi-Source Codes. (Originator drug products are not applicable.)
- The drug product's manufacturer (labeler) cannot be a repackager.
- The drug product must be active.
- The drug product cannot be the superseded part of an NDC Change.
- The drug product's GPI cannot start with "94", "96", "97", "98" (except for GPIs starting with "970510").
- The drug products must have the same Generic Product Packaging Code; however, drug products that have a Unit-Dose/Unit-of-Use Package Code of "U" are in the same calculations as drug products Unit-Dose/Unit-of Use Package Codes of "b" (blank).
- Drug products with "X" Unit-Dose/Unit-of-Use Package Codes are included in a separate calculation, only if all other criteria are met.
- The drug product's GPI cannot be a Partial GPI (GPI Generic Names with asterisks).
- The drug product cannot be a clinic pack.

### Criteria for GEAP Calculation

The following is a list of criteria that must be met in order for Wolters Kluwer Clinical Drug Information to calculate GEAPs:

- The drug products must meet all of the criteria needed for the AAWP calculation.
- The drug products must have TEE Codes beginning with "A" (except for TEE Codes of "A1" and "A2").

### Additional Points to Consider

The following are some additional points to consider regarding AAWP and GEAP

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- Since the value of the GPPC represents the Package Description, Package Size, Package Size Unit of Measure, Package Quantity, and Unit-Dose/Unit-of-Use Package Code, injectable drug products may be subdivided, resulting in an AAWP that is not useful. For example, an Ampicillin injection may come in a single vial, 12 vials, a single ampule, or 12 ampules. Each has a different GPPC and, consequently, a different AAWP and GEAP. Therefore, it may be desirable to average the unit price for GPPCs with the same GPPC-Core and with a Route of Administration of "IV", "IJ", "IM", "SC", or "IT". This price may be more useful for drug products of that generic ingredient and strength.
- The GPPC differentiates drug products with different package sizes. For instance, a pint can be 473 ml or 480 ml. These drug products will have different GPPCs and calculated prices. This same situation occurs for creams and ointments due to the conversion of "ounces" to "grams" when explicit metric sizes are not stated.

### **Pricing Attributes and their Relationships**

#### **Unit Price**

The Unit Price represents the price of an individual unit as defined by the Package Size Unit of Measure. A unit will represent the lowest common denominator (such as EA, GM, ML) for a given drug product.

The Unit Price can be determined by dividing the Package Price by the product of the Package Size multiplied by the Package Quantity.

For dry injectable products that may be reconstituted to variable volumes, the Unit Price represents the price per single dry vial, ampule, or syringe.

Within the GPPC Price File, the Unit Price is applicable to the following price types:

- AAWP
- GFAP

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Within the NDC Price File, the Unit Price is applicable to the following price types:

- AWP
- DP
- WAC
- CMS FUL

The NDC Price File provides an 11-digit Unit Price with five digits to the left of the decimal and six digits to the right. In addition, a 13-digit Unit Price - Extended value is provided with 8 digits to the left of the decimal and five digits to the right.

When the Unit Price is greater than \$99,999,999, the Unit Price is not currently being supplied.

### Package Price

The Package Price represents the price for the entire package and can be determined by multiplying the Unit Price by the product of multiplying the Package Size by Package Quantity.

Unit Price x (Package Size x Package Quantity) = Package Price

Within the NDC Price File, the Package Price is applicable to the following price types:

- AWP
- DP
- WAC
- CMS FUL

### Price Relationships

The following price relationships exist within the data:

The Package Size multiplied by the Package Quantity equals the Total Package Quantity. The AWP Package Price divided by the Total Package Quantity equals the AWP Unit Price.

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### Examples:

Drug Product	Package Size	Package Size Unit of Measure	Package Quantity	Total Package Quantity	AWP Package Price	AWP Unit Price
Crestor	90	EA	1	90	\$470.63	\$5.22922
Gentamicin Sulfate	2	ML	25	50	\$94.50	\$1.89000

### Unit Price/Package Price Rounding

The following price types are supplied to Wolters Kluwer Clinical Drug Information as package prices with two decimals and the unit prices are determined by Wolters Kluwer Clinical Drug Information to five decimal positions\*:

- AWP
- DP
- WAC

In a small number of records, this can result in some precision inconsistencies when converting the Unit Price back to a Package Price. One method to overcome this is to increase the precision of the Unit Price and determine your own Unit Price to seven decimal positions or greater from the package price:

Unit Price = Package Price / (Package Size x Package Quantity)

### Example:

### **Typical Conversion:**

Unit Price = 0.03413 Pack Price = 34.13

Pack Size = 1,000 (GM) Pack Qty = 1

 $0.03413 \times 1,000 = 34.13$  (same as pack price)

### Precision Inconsistency:

Unit Price = 0.01606 Pack Price = 473.91

Pack Size = 29,510 (GM) Pack Qty = 1

 $0.01606 \times 29,510 = 473.93$  (differs from pack price of 473.91)

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Note	If the Unit Price is determined with greater precision by dividing the Pack
	Price by the Pack Size, and then times the Pack Quantity, the following
	result occurs:

473.91 / 29,510 = 0.0160593 0.0160593 x 29,510 = 473.90994 or 473.91 (same as pack price)

The following price type is supplied to Wolters Kluwer Clinical Drug Information as Unit Prices. Precision inconsistencies can occur when converting the Unit Price to Package Prices and then back again:

CMS FUL

This occurs because only two decimal positions are generally included (dollars and cents) in a package price.

### Package Price = Unit Price x Package Quantity

It is possible to determine a Package Price to a greater precision by increasing the number of decimal places, but the price may not be usable as input for many software applications as a result.

The following price types are determined by Wolters Kluwer Clinical Drug Information as Package Prices. Precision inconsistencies can occur when converting the Package Price to Unit Prices and then back again:

- AAWP
- GEAP

Note	MED-File included a six-decimal unit price; however, the current prices a		
	determined to five decimals. You may still see a six-decimal unit price		
	within your data.		

### **Price Effective Date**

The Price Effective Date reflects the date that the manufacturer associates to the price information they provide.

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# **Drug Attributes**

# **Bioequivalence Code**

The Bioequivalence Code is a proprietary Wolters Kluwer Clinical Drug Information concept, assigned to the DDID, that generalizes the Therapeutic Equivalence Evaluation (TEE) Code assigned at the NDC-UPC-HRI level for products sharing a DDID. This code also indicates when the TEE Code cannot be generalized.

For instance, the Bioequivalence Code will be defined as "C" if

- two different packaged drug products (different NDC-UPC-HRI, but share the same DDID) have different TEE Codes (for example: "A1" and "A2")
- when multiple TEE Codes exist for a DDID

### Valid Values are:

Code	Description
Α	Products in same GPI are equivalent
В	Products in same GPI are not equivalent
С	Products may or may not be equivalent
N	Equivalency determination not available
U	Undeterminable (obsolete)

Note	The value of undeterminable (obsolete) is only applicable in previous
	versions of this file.

### **Brand Name Code**

The Brand Name Code is a proprietary Wolters Kluwer Clinical Drug Information concept, assigned to the DDID, that generalizes the Name Type Code assigned at the NDC-UPC-HRI level for products sharing a DDID. The Brand Name Code indicates the type of name used in the Drug Name.

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### Valid Values:

- Trademarked Name any product name that has an associated trademark symbol
- Branded Generic Name any non-trademarked product name that is not the generic ingredient name
- Generic Name any product name that is also the generic ingredient name

### Example:

Trademarked Name (T)	Branded Generic Name (B)	Generically Named (G)
Adoxa Oral Tablet 100 MG	Avidoxyl Oral Tablet 100 MG	Doxycycline Monohydrate Oral Tablet 100 MG
Tylenol Oral Tablet 325 MG	Non-Aspirin Pain Relief Oral Tablet 325 MG	Acetaminophen Oral Tablet 325 MG
Chlor-Trimeton Oral Tablet 4 MG	Aller-Chlor Oral Tablet 4 MG	Chlorpheniramine Maleate Oral Tablet 4 MG

#### Note

In this context, the definition of a Branded Generic Name is a name accepted as an industry standard for a specific formulation used by more than one manufacturer/distributor. This name is also used by non-research and development (generic) manufacturers to represent their version of a generic product.

### **Clinic Packs**

An NDC-UPC-HRI is defined as a Clinic Pack if the drug product is distributed to patients as samples by hospitals, clinics, manufacturers, or physicians. The manufacturer communicates to Wolters Kluwer Clinical Drug Information if a particular NDC-UPC-HRI meets this criteria.

### **Controlled Substance Code**

The Controlled Substance Code, assigned to the DDID, identifies controlled substances, as classified by the Drug Enforcement Administration (DEA). It generalizes the DEA Class Code assigned at the NDC-UPC-HRI level. If more than one code is possible for a DDID, the value of "Undeterminable" is assigned.

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### Valid Values:

Description	Definition	DEA Class
No accepted medical use	High abuse potential; medical use not accepted (such as heroin, marijuana, and LSD)	C-I
High abuse, severe dependence liability	High abuse potential with severe dependence liability (such as narcotics, amphetamines, and barbiturates)	C-II
Moderate dependence liability	Less abuse potential than Schedule II drugs and moderate dependence liability (such as nonbarbiturate sedatives, nonamphetamine stimulants, and limited amounts of certain narcotics)	C-III
Limited abuse potential	Less abuse potential than Schedule III drugs and limited dependence liability (such as some sedatives, antianxiety agents, and non-narcotic analgesics)	C-IV
Limited abuse potential, small amounts	Limited abuse potential; primarily small amounts of narcotics (codeine) used as antitussives or antidiarrheals; under federal law, limited quantities of certain C-V drugs may be purchased directly from a pharmacist without a prescription; can be either prescription or OTC	C-V
DEA Class Code is not applicable	A DEA Class Code is not applicable	N/A
Undeterminable	A DEA Class Code is undeterminable	Undet

### **DEA Class Code**

The DEA Class Code, assigned to the NDC-UPC-HRI, identifies federally controlled substances classified by the Drug Enforcement Administration (DEA).

Description	Definition	DEA Class
No accepted medical use	Schedule I: High abuse potential; medical use not accepted (such as heroin, marijuana, and LSD)	C-I
High abuse, severe dependence liability	Schedule II: High abuse potential with severe dependence liability (such as narcotics, amphetamines, and barbiturates)	C-II

Description	Definition	DEA Class
Moderate dependence liability	Schedule III: Less abuse potential than Schedule II drugs and moderate dependence liability (such as nonbarbiturate sedatives, nonamphetamine stimulants, anabolic steroids, and limited amounts of certain narcotics)	C-III
Limited abuse potential	Schedule IV: Less abuse potential than Schedule III drugs and limited dependence liability (such as some sedatives, anti-anxiety agents, and non-narcotic analgesics)	C-IV
Limited abuse potential, small amounts	Schedule V: Limited abuse potential; primarily small amounts of narcotics (codeine) used as antitussives or antidiarrheals; under federal law, limited quantities of certain C-V drugs may be purchased directly from a pharmacist without a prescription; can be either prescription or OTC	C-V
DEA Class Code is not applicable	A DEA Class Code is not applicable	N/A

Note	State laws may be more stringent than federal laws and must also be
	observed when dispensing controlled substances.

The Controlled Substance Code which is a summarization of the DEA Class Code is assigned to a DDID.

### **DESI Code**

The Food and Drug Administration (FDA) is responsible for assuring drugs are safe and effective for human use. The DESI Code, assigned to the NDC-UPC-HRI, identifies the stage of review for drugs pending final resolutions of efficacy by the FDA's Drug Efficacy Study Implementation (DESI) program. These drugs are currently rated less than effective (LTE) by the DESI program.

"IRS" refers to drugs that are identical, related, or similar to current DESI drugs. "NOOH" refers to Notice of Opportunity for a Hearing, which is published in the Federal Register.

According to the FDA, the following codes are valid. Additionally, Wolters Kluwer Clinical Drug Information includes the value of "b" (blank) for non-drug and other non-applicable items.

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### Valid Values:

Code	Description	Definition
p,	Non-drug and other non-applicable items	Non-drug and other non-applicable items
2	Determined to be safe and effective	Non-DESI/IRS drugs or DESI/IRS drugs determined safe and effective
3	Under review (NOOH has not been issued)	DESI/IRS drugs under review (NOOH has not been issued)
4	Less than effective for some indications	LTE DESI/IRS drugs for some indications
5	Less than effective for all indications	LTE DESI/IRS drugs for all indications
6	Less than effective, withdrawn	LTE DESI/IRS drugs withdrawn from the market

CMS is mandated by the Omnibus Budget Reconciliation Act of 1981 banning reimbursement for LTE drug products (DESI Codes 5 and 6) by federal Medicare and Medicaid agencies.

The Federal Drug Rebate program, as part of the Omnibus Budget Reconciliation Act of 1990, requires labelers to submit the DESI status of a drug to CMS.

State Medicaid programs determine coverage of certain drugs based in part on the DESI status of the drug. The CMS FUL is not available to states for specific DESI classes of drugs.

Medicaid coverage for drug items based on the DESI status of the drug is reflected in the table below:

Coverage/Rebate/FFP	DESI Code				
Requirements	2	3	4	5	6
Mandatory coverage under Medicaid Drug Rebate Program	Х		*		
May be excluded or restricted under Medicaid Drug Rebate Program		Х			
Optional coverage under Medicaid		Х	Х		
Subject to rebate payments	Х	Х	*		
FFP is available	Х	Х	Х		
FFP is not available				Х	Х

Note

\* If a drug in this group has an FDA-approved labeled indication for which a NOOH has NOT been issued, the drug is covered for that indication and other medically accepted indications and the drug is subject to rebate.

The Efficacy Code which is a summarization of the DESI code is assigned to a DDID.

### **Dollar Rank Code**

The Dollar Rank Code is a proprietary Wolters Kluwer Clinical Drug Information concept assigned to the NDC-UPC-HRI that indicates the drug product's annual industry dollar sales rank according to independent survey results. Similar drug products with different strengths or package sizes, thus different NDC-UPC-HRIs, may have different Dollar Rank Codes.

Wolters Kluwer Clinical Drug Information updates this information annually in the spring and notifies customers when the update occurs.

The Dollar Rank is defined as follows:

- Ranked between 1 and 100
- Ranked between 101 and 200
- Ranked between 201 and 300
- Ranked between 301 and 400
- Ranked between 401 and 500

For drugs that are outside the top 500, no ranking is provided.

### **Dosage Form**

The Dosage Form is a proprietary Wolters Kluwer Clinical Drug Information concept defining the form in which the drug product is dispensed.

Wolters Kluwer Clinical Drug Information associates dosage forms used by manufacturers to available Wolters Kluwer Clinical Drug Information dosage forms.

### For example:

Manufacturer-described Dosage Form	Wolters Kluwer Clinical Drug Information Dosage Form
12 Hour Extended Release Tablet	Tablet Extended Release 12 Hour
12 Hour Sustained Release Tablet	
12 Hour Controlled Release Tablet	
Enteric Coated Tablet	Delayed Release Tablet
Spray	Liquid

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Drops	Liquid, Solutions, or Suspension (as appropriate)
Sponge	Miscellaneous
Therapy Pack	Miscellaneous

A dosage form of Miscellaneous is used when an appropriate Wolters Kluwer Clinical Drug Information dosage form is not available, when the drug product includes a combination of drugs with varying dosage forms (such as tablet and liquid), or in other situations when a dosage form may not be applicable.

The dosage form is included in several places within MED-File v2:

- As an attribute of the DDID in the Drug Name File
- As a component of several of the proprietary Wolters Kluwer Clinical Drug Information drug name concepts
- Within the structure of the Generic Product Identifier (GPI) in the sixth subset (11<sup>th</sup> and 12<sup>th</sup> characters).

The same dosage forms are used in all instances, although the codified values used to define them may vary based on the file in which they reside.

#### Note

The four-character Dosage Form code is not to be displayed or provided in print form in end-user applications. The code should be translated to its corresponding Value Description as defined in the Validation/Translation File. Use of the Value Abbreviation is also discouraged. Significant patient safety issues are associated with the use of non-standard abbreviations such as those found in the Dosage Form code and its corresponding Value Abbreviation. Similarly, the Description File provides an Abbreviated Textual Description for the Dosage Form. This abbreviated representation of the Dosage Form is not to be displayed or provided in print form in end-user applications.

For a complete list of their current values, go to Appendix D, Dosage Form Codes.

# **Efficacy Code**

The Food and Drug Administration (FDA) is responsible for assuring drugs are safe and effective for human use. The Efficacy Code, assigned to the DDID, is a generalization of the DESI Code that is assigned to the NDC-UPC-HRI. The DESI Code identifies the stage of review for drugs pending final resolutions of efficacy by the FDA's Drug Efficacy Study Implementation (DES) program. These drugs are currently rated Less Than Effective (LTE) by the FDA's DESI program.

Documentation Manual 2-43 Published: 11/11 Revised: 04/18 "IRS" refers to drugs that are identical, related, or similar to current DESI drugs. "NOOH" refers to Notice of Opportunity for a Hearing, which is published in the Federal Register.

2-44 MED-File v2 Published: 11/11 Revised: 04/18 According to the FDA, the following codes are valid. Additionally, Wolters Kluwer Clinical Drug Information includes the value of "b" (blank) for non-drug and other non-applicable items.

### Valid Values:

Code	Description	Definition
p,	Non-drug and other non- applicable items	Non-drug and other non-applicable items
2	Determined to be safe and effective	Non-DESI/IRS drugs or DESI/IRS drugs determined to be safe and effective
3	Under review (NOOH has not been issued)	DESI/IRS drugs under review (NOOH has not been issued)
4	Less than effective for some indications	LTE DESI/IRS drugs for some indications
5	Less than effective for all indications	LTE DESI/IRS drugs for all indications
6	Less than effective, withdrawn	LTE DESI/IRS drugs withdrawn from the market
U	Undeterminable	An Efficacy Code is undeterminable

CMS is mandated by the Omnibus Budget Reconciliation Act of 1981 banning reimbursement for LTE drug products (DESI Codes 5 and 6) by federal Medicare and Medicaid agencies.

The Federal Drug Rebate program, as part of the Omnibus Budget Reconciliation Act of 1990, requires labelers to submit the DESI status of a drug to CMS.

State Medicaid programs determine coverage of certain drugs based in part on the DESI status of the drug. The CMS FUL is not available to states for specific DESI classes of drugs.

Medicaid coverage for drug items based on the DESI status of the drug is reflected in the table below:

Coverage/Rebate/FFP	DESI Code				
Requirements	2	3	4	5	6
Mandatory coverage under Medicaid Drug Rebate Program	Х		*		
May be excluded or restricted under Medicaid Drug Rebate Program		Х			
Optional coverage under Medicaid		Х	Х		
Subject to rebate payments	Х	Х	*		
FFP is available	Х	Х	Х		
FFP is not available				Х	Х

Note

\*If a drug in this group has an FDA-approved labeled indication for which a NOOH has NOT been issued, the drug is covered for that indication and other medically accepted indications and the drug is subject to rebate.

### **Form Type Code**

The Form Type Code is a proprietary Wolters Kluwer Clinical Drug Information concept assigned to the DDID that indicates the form of the drug when the medication is administered to a patient. This form may be different than the form which is packaged and sold by the manufacturer and therefore, may differ from the Dosage Form. The value is generalized to represent all products sharing the same DDID. The Form Type may be:

- Gas
- Liquid
- Solid
- Other

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### Examples:

Drug	Form Type	Dosage Form
Ethyl Chloride External Aerosol	Gas	Aerosol
Miralax Oral Powder	Liquid	Powder
Nexcare Skin Protectant Wipes	Other	Miscellaneous
Advil PM	Solid	Capsule
Clobetasol Propionate	Solid	Ointment

### **Innerpacks**

An NDC-UPC-HRI is defined as an innerpack when the manufacturer reports an internal packaging NDC-UPC-HRI that is associated to the NDC-UPC-HRI on a carton. The manufacturer does not provide pricing on the innerpack. Its pricing is determined from the carton and is updated when a price change occurs to the carton. Innerpacks may not be sold separately by the manufacturer. However, they may be sold individually by the wholesaler.

### Internal-External Code

The Internal-External Code is a proprietary Wolters Kluwer Clinical Drug Information concept, assigned to a DDID, that indicates whether the drug is administered internally, externally, or both. The value is generalized to represent all products sharing a DDID. It complements the Route of Administration for a drug product.

### **Examples:**

Drug	Internal-External	Route
Dulcolax Bowel Prep Kit	Combination of Internal and External	Combination
Dulcolax Oral Tablets 5 MG	Internally administered	Oral
Dulcolax Rectal Suppository 10 MG	Externally administered	Rectal
BD SafetyGlide Insulin Syringe	Different than above	Does not apply

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### Labelers

Within MED-File v2, manufacturers are referred to as labelers. The broader term, labeler, includes those that manufacturer drug products as well as those that repackage or distribute products.

The following information describes the data associated with labelers.

### Labeler Type Code

The Labeler Type Code is a proprietary Wolters Kluwer Clinical Drug Information concept that helps differentiate among manufacturers that produce products that are promoted as follows:

Description	Definition
Promoted as "Brand"	Labeler's products are priced or promoted as "Brand," "Originator," or "Innovator" products
Promoted as "Generic"	Labeler's products are priced or promoted as "Generic" products
Promoted as "Brand" or "Generic"	Labeler's products are priced or promoted as either "Brand" or "Generic" products

Note	The Labeler Type Code may change as labelers merge or as market
	strategies change.

### Medi-Span Labeler Identifier

The Medi-Span Labeler Identifier is a proprietary Wolters Kluwer Clinical Drug Information concept that links the drug product (NDC-UPC-HRI) to its manufacturer or distributor. Most Medi-Span Labeler Identifiers are derived from the labeler code segment of the NDC. However, in some cases, the Medi-Span Labeler Identifier differs from the labeler code segment of the NDC, so that the accurate division name within the manufacturer or distributor can be associated with the drug product. The Medi-Span Labeler Identifier may also differ from the labeler code segment of the NDC when a company purchases another product line and has yet to convert the products to their labeler code.

For example, the Medi-Span Labeler Identifier "00074" for E.E.S. tablets corresponds to the labeler code segment of the NDC. However, for Rondec and Aminosyn, the Medi-Span Labeler Identifier used to assign the manufacturer name is not the same as the labeler portion of their respective NDCs.

2-48 MED-File v2 Published: 11/11 Revised: 04/18 Wolters Kluwer Clinical Drug Information has created division-specific Medi-Span Labeler Identifiers to show actual manufacturer names or divisions. A complete list of Medi-Span Labeler Identifiers and Labeler Descriptions is available upon request from Wolters Kluwer Clinical Drug Information's Customer Support Division.

### Manufacturer's (Labeler) Name

The Manufacturer's (Labeler) Name indicates the manufacturer, distributor, and/or division whose name is included on the drug product label.

MED-File v2 lists virtually every manufacturer and distributor in the United States. A complete list of Labeler Names and Labeler Abbreviated Names is available upon request.

### Manufacturer's Abbreviated Name

The Manufacturer's Abbreviated Name indicates the shortened name for the manufacturer, distributor, and/or division whose name is included on the label. A complete list of Labeler Names and Labeler Abbreviated Names is available upon request.

### Examples:

Medi-Span Labeler Identifier	Manufacturer's (Labeler) Name	Manufacturer's Abbreviated Name	Labeler Type
00067	NOVARTIS	NOV CON HE	Brand
00078	NOVARTIS	NOVARTIS	Brand
00904	MAJOR PHARMACEUTICALS	MAJOR	Generic
17191	BAXA CORPORATION	BAXA CORP	Both Brand and Generic
55513	AMGEN	AMGEN	Brand

# **Legend Indicator Code**

The Legend Indicator Code, assigned to the DDID, indicates Federal Prescription (Rx) (legend) or Over-the-Counter (OTC) (non-legend) status. The Legend Indicator Code generalizes the RX-OTC Indicator Code, assigned at the NDC-UPC-HRI, for all products sharing a DDID. If more than one code is possible for a DDID, the Legend Indicator Code value is "Undeterminable".

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### Local/Systemic Code

The Local/Systemic Code is a proprietary Wolters Kluwer Clinical Drug Information concept, assigned to a DDID, that indicates whether the drug product has a local or systemic effect. The value is generalized to represent all products sharing the same DDID. The information is primarily utilized within Wolters Kluwer Clinical Drug Information's drug interactions module to allow for interaction alerts to be differentiated based on whether the drug has local or systemic effects.

The values for the Local/Systemic Codes are:

- Local
- Oral
- Parenteral
- Systemic
- Undetermined
- Does Not Apply

### Examples:

Drug	Local/Systemic
Afrin Nasal Spray Nasal Solution 0.05%	Local
Morphine Sulfate Injection Solution 8 MG/ML	Parenteral
Morphine Sulfate Oral Tablet 8 MG	Oral
Morphine Sulfate Rectal Suppository 10 MG	Systemic
Morphine Sulfate Powder	Does Not Apply

### **Maintenance Drug Code**

The Maintenance Drug Code is a proprietary Wolters Kluwer Clinical Drug Information concept assigned to a DDID. Third Party Administrators (TPAs) may have provisions to provide maintenance drugs in quantities greater than the standard 30-day supply. Often, a drug's use in a specific patient for a particular indication may be a more relevant determination of a maintenance drug. Consequently, the Maintenance Drug Code is provided as a general guideline. Drugs meeting the following criteria are considered maintenance drugs by Wolters Kluwer Clinical Drug Information:

- The drug is typically a self-administered therapy.
- The drug has low probability for dosage or therapy changes due to side effects, serum drug concentration monitoring, or therapeutic response

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- over a course of prolonged therapy. Therefore, it is cost-effective to dispense the drug in quantities greater than the standard supply.
- The drug's most common use is to treat a chronic disease state when a therapeutic endpoint cannot be determined. Therapy with the drug is not considered curative. A drug may have an indication for maintenance therapy but lacks the Maintenance Drug Code if that indication is not the most common.
- The drug is usually administered continuously rather than intermittently (prn or as needed) and typically for a period of 12 months or longer (for example, a diuretic to treat hypertension, but not prenatal vitamins).

These criteria are limited to typical outpatient use of a drug. Dosage forms that are not typical for outpatient dispensing (such as injections that are not selfadministered) may be excluded. Non-drug or device products and nonprescription drug products, with the exception of insulin, are generally excluded.

### Examples:

Drug	Maintenance Drug Code
Captopril-Hydrochlorothiazide Oral Tablet 5-25 MG	Maintenance Drug
Simvastatin Oral Tablet 10 MG	Maintenance Drug
Amoxicillin-Pot Clavulanate Oral Suspension Reconstituted 125-31.25 MG/5ML	Not a Maintenance Drug
HalfLytely with Flavor Packs Oral Kit 5-210 MG-MG	Not a Maintenance Drug

End-users may have special definitions of maintenance drugs. Tables can be created, using the GPI, to allow end-users to define maintenance drugs specific to their patient population or third-party plan.

The Maintenance Drug Code assigned to a DDID can change over time. The change could be the result of:

- Drug Indication change: If it can be determined that the primary use of a drug has changed over time, then the Maintenance Drug Code may change as a result.
- More drug information becomes available: If more information or clarification about the drug and/or its maintenance use becomes available, then the Maintenance Drug Code may change.
- GPI Change to a product: A change to the product's GPI may cause the Maintenance Drug Code to change. This may be the result of incorrect or updated information from the labeler, for example, that may cause the product's GPI to change.

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### **Modifiers**

Modifiers represent a proprietary Wolters Kluwer Clinical Drug Information concept that is assigned to the NDC-UPC-HRI. Modifiers provide supplemental information about the NDC-UPC-HRI that is not provided by other drug file attributes. This information can be used to identify unique information about the drug product.

There are three types of Modifiers:

- Package Modifiers
- Product Modifiers
- Trademark Modifiers

**Note** Zero, one, or many modifiers are assigned to an NDC-UPC-HRI.

### **Modifier Code**

Effective March 1, 2018, Wolters Kluwer Clinical Drug Information will report only active ingredients for compounded products from outsourcing facilities. All other product modifiers will not be applicable for compounded products from outsourcing facilities. Products from outsourcing facilities may be identified by using the Limited Distribution Code of 03.

The Modifier Code is comprised of three two-character subsets. The first subset defines the Modifier Type as follows:

Value	Description
AA	Package Modifiers
BB	Product Modifiers
TT	Trademark Modifiers

The first and second subsets define the Modifier Type and Modifier Category.

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# Examples of Package Modifiers include:

Values	Description
AA AA	Vial Sizes
AA AB	Parenteral Packaging Descriptions
AA AC	Needle Lengths and Gauges
AA AD	Non-Parenteral Packaging Descriptions
AA AE	Neonatal/Pediatric Packaging
AA AF	Package Size
AA AG	Item Size Description

### **Examples of Product Modifiers include:**

Value	Description
BB AA	Colors
BB AB	Flavors
BB AC	Base Types
BB AD	Dosage Forms
BB AE	Shapes
BB AF	Free Descriptions (such as Dye Free and Alcohol Free)
BB AG	Fragrance

### Note

Colors, Flavors, Base Types, Dosage Forms, Shapes, and "Free" Descriptions are included when multiple original drug products are available. These descriptions differentiate generic drug products mimicking original drug products. A color Product Modifier is not present if an NDC-UPC-HRI is available in more than one color.

### Examples of Trademark Modifiers include:

Value	Description
TT AA	Trademark Packaging Terms
TT AB	Trademark Dosage Forms

The first, second, and third subsets represent the full Modifier Code, defining the Modifier Type, Modifier Category, and the specific Modifier Code within a category.

### **Modifier Description**

Each Modifier Code is represented by a description.

Examples of Modifier Codes and their descriptions include:

Modifier Code	Modifier Description
AAAA28	500 ML
AAAA73	2 CARTONS OF 30 EACH
AAAB38	W/LUER LOCK
AAAB9D	W/O DILUENT

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Modifier Code	Modifier Description
AAABN3	PRECISIONGLIDE NEEDLE
AAAC50	25G X 5/8
BBAAER	WHITE/PURPLE
BBAB96	CHERRY-VANILLA
BBAC7P	NON-ALKALINE
BBAD37	SOFTGEL(S)
BBAE23	RECTANGULAR
BBAF51	TALK FREE
BBAI01	MEDICAL FOOD
BBAI03	AUTHORIZED GENERIC
TTAA64	CONVENIENCE PACK
TTAAD3	AMBU-FLEX III
TTAABN4	DUOTAB

For a complete list of Modifier Codes and Modifier Descriptions, refer to the contents of the Modifier File.

### **Multi-Source Code**

The Multi-Source Code is a proprietary Wolters Kluwer Clinical Drug Information concept assigned to an NDC-UPC-HRI that identifies drug products as either single- or multiple-source original drug products or a generic copy of the standard drug product.

### Current values are:

Code	Description	Definition
N	Single-source product	Single-source product available from one labeler.
М	Single-source, co-licensed product	Product is co-licensed and considered a single-source product despite being available from multiple labelers.
0	Multi-source, originator prod- uct	Product available from multiple labelers; however, this is considered to be the originator (industry standard) product.
Υ	Multi-source product	Multi-source product available from multiple labelers.

### Examples:

Condition	N	M	0	Υ
Single-Source	Lantus Inj	-	-	-
Co-license	-	Adderal XR Oral Capsule Extended Release 24 Hour 10 MG AND Amphetamine- Dextroamphetamine Oral Capsule Extended Release 24 Hour 10 MG	-	-
Original with	-	-	Valium 5	Diazepam
Generics			mg	5 mg
Former Co- licensing with	-	-	Septra DS	SMZ/TMP DS
Generics			Bactrim	Sulfameth
			DS	oxazole/
				Trimethop
				rim DS

This code is provided by Wolters Kluwer Clinical Drug Information as a general guideline. Additional factors such as TEE Code, pricing, and so on may be needed to determine whether generic substitution between drug products is appropriate. Wolters Kluwer Clinical Drug Information recognizes that one use of the Multi-Source Code is to differentiate "brand name" from "generic" products in various third-party drug benefit programs. Applications include mandatory generic utilization, differential fees, and differential co-pay plans. Such applications are based on the assumption that the "brand name" product is more expensive than "generic" equivalents; however, this assumption is not always true. In a few drug categories, the originator product is priced at or below comparable generic products. Therefore, Wolters Kluwer Clinical Drug Information codes drug products as "multi-source" (Y) and designates no originator (O) product in these categories.

Wolters Kluwer Clinical Drug Information's determination of a multi-source product requires the product to be pharmaceutically equivalent but not necessarily bioequivalent. Repackaged products carry the multi-source code of their brand counterparts and are not considered in the determination of "multi-source" products. Pharmaceutically equivalent products share the same active ingredient(s), route, dosage form, metric strength, and strength unit of measure. Characterizations such as color, shape, flavor, packaging, preservatives, expiration date, and inactive ingredients are not considered in Wolters Kluwer Clinical Drug Information's generic product determination. The GPI can be used to find these pharmaceutical equivalent products. The TEE

2-56 MED-File v2 Published: 11/11 Revised: 04/18 Code is used to determine bioequivalency of pharmaceutically equivalent drug products.

### **Multi-Source Summary Code**

The Multi-Source Summary Code is a proprietary Wolters Kluwer Clinical Drug Information concept, assigned to the DDID, that generalizes the Multi-Source Code assigned at the NDC-UPC-HRI level for products sharing a DDID. The values and definitions for the Multi-Source Summary Code are the same as those for the Multi-Source Code, described above.

### **Name Source**

The Name Source is a proprietary Wolters Kluwer Clinical Drug Information concept assigned to a DDID that indicates whether the drug name came from the Generic Product, the Product, or both the Generic Product and the Product. When a patented brand name drug is initially marketed, a brand name is created (for example, Crestor). A generically defined drug name is also created (for example, Rosuvastatin Calcium) even though the drug is not marketed in generic form at that time. Thus, the Name Source for Rosuvastatin Calcium is the Generic Product. Conversely, the drug name Simvastatin is marketed as a Product and also represents the Generic Product name for the brand drug Zocor.

### Examples:

Drug	Name Source	
Crestor Oral Tablet 5 MG	Product	
Rosuvastatin Calcium Oral Tablet 5 MG	Generic Product	
Simvastatin Oral Tablet 40 MG	Generic Product and Product	

### Name Source Code

The Name Source Code indicates if at least one NDC is marketed with this drug description or if a generic drug description has been created.

### Examples:

Drug	Name Source Code	Brand Name Code
Crestor Oral Tablet 5 MG	Product does exist in NDC file	Trademarked Name

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Rosuvastatin Calcium Oral Tablet 5	Product does not exist	Generic Name
MG	in NDC File	

When generic-named drugs are initially introduced to the market, the Name Source Code will change from a "Product does not exist in NDC File" to "Product does exist in NDC File". When generic-named drugs are removed from the market, this value will change from "Product does exist in NDC File" to "Product does not exist in NDC File".

Note

The Name Source Code does **not** indicate the type of name. Refer to the Brand Name Code for this information. Generic drug product records can have either Name Source Code.

### Name Type Code

The Name Type Code is a proprietary Wolters Kluwer Clinical Drug Information concept assigned to the NDC-UPC-HRI that indicates the type of name assigned to the drug.

Values for the Name Type Code are defined as follows:

- Trademarked Name
- Branded Generic Name
- Generic Name

### Example:

Trademarked Name (T)	Branded Generic Name (B)	Generically Named (G)
Esgic Oral Capsule 50-325-	Margesic Oral Capsule	Butalbital-APAP-Caffeine
40 MG	50-325-40 MG	Oral Capsule 50-325-40 MG
Tylenol Oral Tablet 325 MG	Non-Aspirin Pain Relief Oral Tablet 325 MG	Acetaminophen Oral Tablet 325 MG
Chlor-Trimeton Oral Tablet	Aller-Chlor Oral Tablet	Chlorpheniramine Maleate
4 MG	4 MG	Oral Tablet 4 MG

Note

In this context, the definition of a Branded Generic Name is a name accepted as an industry standard for a specific formulation used by more than one manufacturer/distributor. This name is also used by non-research and development (generic) manufacturers to represent their version of a generic product.

2-58 MED-File v2 Published: 11/11 Revised: 04/18 The Brand Name code which is a summarization of the Name Type Code is assigned to a DDID.

# **Packaging**

Drug product packaging is assigned to an NDC-UPC-HRI through the Generic Product Packaging Code (GPPC). There are five packaging-related fields. The unique combination of these fields establishes the GPPC-sufflix. All NDC-UPC-HRIs with the same GPPC-suffix will share the same packing.

## Relationship of Packaging Fields

Drug Prod- uct	Pkg Size	Package Size Unit of Mea- sure	Package Quantity	Total Package Quantity	Package Description	Unit Dose/ Unit- of-Use
Crestor	100	Each	1	100	Вох	Unit Dose
Crestor	90	Each	1	90	Bottle	
Omnaris	12.5	Gram	1	1	Inhaler	Unit-of-Use
Ampicil- lin Sodium Injec- tion*	1	Each	10	10	Vial	Unit Dose

Note

\*For vials and ampules reconstituted to a variable volume, "1" is used as the Package Size (regardless of the reconstituted volume), and the Package Quantity is the number of vials or ampules in the box or case. The "1" is also used in situations when a metric quantity cannot be expressed.

Each field describes a portion of the packaging. Depending on the needs of the end-user, some applications may require the Package Size and Package Size Unit of Measure, while others may require the Package Size, Package Size Unit of Measure, and Package Quantity.

Additional packaging information is available in the form of Modifiers that do not relate to these standard fields.

## Package Descriptions

The Package Description is a proprietary Wolters Kluwer Clinical Drug Information concept that indicates the container or package used for the drug product. The following is a list of the current package descriptions:

Description
Ampule
Atomizer
Bag
Blister
Bottle
Вох
Can
Cartridge
Сир
Crtrdg-NDL
Disp Pack
Drum
Flex Cont
Glass Cont
Inhaler
Jar
Pack
Pump BtI
Plas Cont
Punchcard
Package
Packet
Pen
Roll
Spray Btl
Sachet
Strip
Stick
Syringe
Tube
Vial

## **Package Quantity**

The Package Quantity identifies the number of individual containers or units per package as supplied by the manufacturer.

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#### Package Size

The Package Size represents the total size of the package in volume or number of units contained. In oral suspensions for reconstitution, the Package Size after reconstitution is the number shown in this field, as stated by the manufacturer.

Unit of use packets with quantity of less than one become a quantity of one each. For injectables that can be reconstituted to a variable volume, the Package Size is "1".

## Package Size Unit of Measure

The Package Size Unit of Measure identifies the unit of measure for the Package Size of the solid, liquid, or gas as dispensed. Wolters Kluwer Clinical Drug Information's assignment of this value is in accordance with the standards set forth by the NCPDP.

Current values are:

Description
Each
Gram
Milliliter

Unit of use packets with a quantity of less than one become a quantity of one each. For injectables that can be reconstituted to a variable volume, the Pack Size Unit of Measure will be "EA".

## Unit-Dose/Unit-of-Use Packaging

Drug products are identified as Unit-Dose or Unit-of-Use based on the following definitions. If the drug product does not meet either of these criteria, it is considered to have standard packaging.

Current values are:

Description	Definition
Unit-Dose Packaging	Any drug product packaged and intended for administration as a single dose at one time. These drug products also maintain complete labeling (UD cup, Strip Packaging tablet/capsule, packet of 2 tablets/capsules that constitute a single dose); this includes all single-dose injections (such as PTV, SDV, amps, syringes, and partial fills).

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Unit-of-Use Packaging	Any packaged drug product in a standard quantity for a specific therapy suitable for direct dispensing to the patient. Examples include repackaged products, tubes of semisolids, potassium chloride powder packets, nicotine gum, and bulk over-the-counter products.
Standard Packaging	Any drug product in which portions are removed for administration and dispensing. This portion does not have labeling for a single-dose unit.

# Repackage Code

The Repackage Code is a proprietary Wolters Kluwer Clinical Drug Information concept, assigned to an NDC-UPC-HRI, that identifies whether products have been repackaged for use by:

- mail order suppliers
- home health care agencies
- · nursing homes
- physicians
- others

Repackaged products include both brand name and generic drug products.

Generally, the repackager status is based on the Labeler. However, Wolters Kluwer Clinical Drug Information may override this status at the product level. Repackager status is communicated to Wolters Kluwer Clinical Drug Information by the manufacturer.

Note	MED-File v2 does not associate a repackaged product to the original source
	product.

## **Reference Brands**

The following information outlines the policy for determining reference brands:

- When multiple brand names exist based on the drug's GPI, the originator (multi-source equals "singe source" or "multi-source, originator) is designated as the reference brand.
- Additional brands and/or inactive brands may be designated as the reference brand, based on customer input. Inactive drugs will cease to be the reference brand once they are inactive for > 48 months.
- If there is only one brand name (multi-source equals "single source" or "multi-source, originator), it will be the reference brand, regardless of its active or inactive status.

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- Products that are co-licensed may all be designated as the reference brand.
- Branded generics may be considered the representative brand if no trade name products exist.
- Generally, there is no reference brand when
  - > All names for a GPI are generic
  - > All names have a multi-source equal to "single source" or "multi-source" but no brand names exist
  - > The GPI is a partial GPI
  - > The item is a bulk chemical
  - > The GPI begins with "97"

## Representative GPI

The Representative GPI is a proprietary Wolters Kluwer Clinical Drug Information concept assigned to a DDID. When multiple GPIs are associated to a DDID, a representative is assigned based on the following criteria:

- New formulation
- Active NDC-UPC-HRI
- Most common GPI assigned
- Most appropriate nomenclature between the GPI and DDID description

## Representative KDC

A representative ingredient set may be assigned to a DDID when multiple ingredient sets exists. The Representative KDC is the KDC assigned to that representative ingredient set.

## **Route of Administration**

The Route of Administration is a proprietary Wolters Kluwer Clinical Drug Information concept that defines how the medication, in the defined dosage form, is administered to the patient.

Wolters Kluwer Clinical Drug Information associates routes uses by manufacturers to available Wolters Kluwer Clinical Drug Information routes.

## Example:

Manufacturer-defined Route	Wolters Kluwer Clinical Drug Information Route
Product can be administered IM or IV	Injection
Product can be administered SC or IV	Injection
Product administered outside the body	In Vitro
Device or Not Applicable Route	Does not apply
Product Kit with Oral and Topical	Combination

The route of administration is included in several places within MED-File v2:

- As an attribute of the DDID in the Drug Name File
- As a component of several of the proprietary Wolters Kluwer Clinical Drug Information drug name concept files
- Implied through the assignment of the GPI

The same routes are used in all instances, although the codified values used to define them may vary based on the file in which they reside.

#### Current routes are:

Route	Comment	
BUCCAL	Administered inside the mouth on the mucosa of the cheek	
COMBINATION	More than one route, excluding route combinations that only include injectable sites	
DENTAL	Application to teeth or gums	
DOES NOT APPLY	Use of a route does not apply	
EPIDURAL*	Injection upon or outside of the dura mater	
EXTERNAL Applied externally to the skin or hair		
IMPLANT	Placing a drug form, drug delivery device, or other device at the desired administration site by insertion into a body tissue or body cavity by surgical or other appropriate insertion proce- dures	
IN VITRO	Not taken internally or applied externally to a patient's body	
INHALATION	Drug administration into the lungs (either during a drawn or forced breath)	
INJECTION	A set of one or more injectable routes or the route of injection is not specified	
INTRA-ARTERIAL*	Injection into an artery or intra-arterial port	
INTRA-ARTICULAR*	Injection into a joint	

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Route	Comment	
INTRACAVERNOSAL*	Injection into the corpora cavernosa	
INTRADERMAL*	Injection within the epidermis (skin)	
INTRAMUSCULAR* Injection into a muscle group		
INTRAOCULAR	Injection, implantation or surgical irrigation within the eyeball	
INTRAPERITONEAL	Administration into the intraperitoneal cavity commonly by injection or instillation into an intraperitoneal catheter port	
INTRAPLEURAL	Injection into the pleura or pleural cavity	
INTRATHECAL*	Injection into a subarachnoid or subdural space	
INTRAUTERINE	Administered within the uterus	
INTRAVENOUS*	Injection directly into a vein or into a venous line port	
INTRAVESICAL	Administered into the bladder	
IRRIGATION	To flush a body cavity or site with a stream of liquid	
MOUTH/THROAT	Applied to a mucus membrane of the oral cavity or throat	
NASAL	Administered via the nose	
OPHTHALMIC	Administered onto the surface of the eyeball or into the conjuctival sac	
ORAL	Taken by mouth	
OTIC	Commonly administered into the external ear canal	
PERFUSION	Administration (pumping) of a fluid through an organ or tissue	
RECTAL	Administered into the rectum (in the anal canal beyond the anal sphincter)	
SUBCUTANEOUS*	Injection through the skin into the loose subcutaneous tissue under the skin	
SUBLINGUAL	Administered under the tongue	
TRANSDERMAL	Applied topically (e.g., patch or ointment) with absorption through the skin for systemic effect	
TRANSLINGUAL	Drug absorption through the tongue into systemic circulation after application on the tongue	
URETHRAL	Administered via insertion or instillation into the uretha	
VAGINAL	Administered into the vagina	

<sup>\*</sup> These Codes are used for drug products limited to this particular route. If more than one route of injection is applicable or if the route of injection is not specified, "IJ" is used.

Note	The comments are for informational purposes only and are not included in
	the data.

#### Note

The 2-character Route of Administration code is not to be displayed or provided in print form in end-user applications. The codes should be translated to its corresponding Value Description as defined in the Validation/Translation File. Use of the Value Abbreviation is also discouraged. Significant patient safety issues are associated with the use of non-standard abbreviations such as those found in the Route of Administration code and its corresponding Value Abbreviation. Similarly, the Description File provides an Abbreviated Textual Description for the Route. This abbreviated representation of the Route is not to be displayed or provided in print form in end-user applications.

## **RX-OTC Indicator Code**

The RX-OTC Indicator Code, assigned to the NDC-UPC-HRI, indicates Federal Prescription (Rx) (legend) or Over-the-Counter (OTC) (non-legend) status. If coded "R", the item requires a prescription; if coded "O", the item is an OTC product. This information is obtained from the manufacturer's product labeling.

The Legend Indicator Code which is a summarization of the RX-OTC Indicator Code, is assigned to a DDID.

## Rx Rank Code

The Rx Rank Code is a proprietary Wolters Kluwer Clinical Drug Information concept assigned to the NDC-UPC-HRI that indicates the drug product's annual prescription velocity according to independent survey results. Similar drug products with different strengths or package sizes, thus different NDC-UPC-HRIs, may have different Rx Rank Codes.

Wolters Kluwer Clinical Drug Information updates this information annually in the spring and notifies customers when the update occurs.

The Rx Rank is defined as follows:

- Ranked between 1 and 100
- Ranked between 101 and 200
- Ranked between 201 and 300
- Ranked between 301 and 400
- Ranked between 401 and 500

For drugs that are outside the top 500, no ranking is provided.

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## Strength

The Strength, in combination with the Strength Unit of Measure, is assigned to the DDID in the Drug Name File. The same Strength and Strength Unit-of-Measure values are also included as attributes in the Dispensable Drug File.

Within the Generic Product Identifier (GPI), the strength and strength-unit-of measure are defined in the seventh subset (13<sup>th</sup> and 14<sup>th</sup> characters).

# **Strength Unit-of-Measure**

The Strength Unit of Measure, when combined with the Strength, represents the dosage strength as provided by the manufacturer. Standards defined by the National Council for Prescription Drug Programs (NCPDP) are applied when establishing the Strength Unit-of-Measure.

Some current values are:

Strength	Description	Strength	Description
%	Percent	MG	Milligram
AHFU	Antihemophilic factor unit	MG-HR	Milligram/hour
GM	Gram	MG/ML	Milligram/milliliter
GM/ML	Gram/milliliter	MINIM	Minim
MCG/ML	Microgram/milliliter	SQ CM	Square centimeter
MEQ	Milliequivalent	UNIT	Unit
MEQ/L	Milliequivalent/liter	UNIT/GM	Unit/gram
MEQ/ML	Milliequivalent/ milliliter	UNIT/ML	Unit/milliliter

To view a table of examples, go to the Drug Descriptor Identifier section.

When there is no strength, the Strength and Strength Unit-of-Measure fields will be blanks. Examples include devices and bulk powders used in compounding.

## **TEE Code**

The Therapeutic Equivalence Evaluation (TEE) Code, assigned to the NDC-UPC-HRI, provides the FDA rating of the therapeutic equivalence of a drug product with other pharmaceutically equivalent drug products, as published in the *Orange Book*. This code can be used in conjunction with the Generic Product Identifier to isolate equivalent drug products.

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In compiling the TEE Code, Wolters Kluwer Clinical Drug Information utilizes the FDA's *Orange Book* or other sources. The absence of a code does not necessarily imply a product is without New Drug Application (NDA) approval. The FDA can re-evaluate codes for specific NDAs, and those changes will be reflected as they become available.

TEE Codes are included only for multiple-source prescription drug products approved for safety and efficacy by the FDA. Products which do not require FDA approval (for example, those manufactured before 1938) do not have TEE Codes. OTC products are generally not evaluated. Inactive drug products retain the TEE Codes that they had at the time of inactivation.

The *Orange Book* lists products according to the name of the firm that has obtained the NDA approval. This firm may be the product manufacturer, product labeler, or distributor. The FDA does not correlate the list of approved products with specific products as they are identified in the market.

Interpretation and evaluation of the TEE Code requires an understanding of the specific policies and definitions of the FDA. For this information, the end-user can refer to the introduction in the *Orange Book*.

The table below provides a list of the TEE Codes currently in use in MED-File v2:

Code	Description	Definition
AA	No Bioequivalence Problems	Products having no bioequivalence problems in conventional dosage forms
AB	Bioequivalence Resolved	Products meeting necessary bioequivalence requirements
AN	Soln/Powd Aerosol - OK	Solutions and powders for aerosolization
AO	Injectable Oil Solutions - OK	Injectable oil solutions (same concentration and vehicle)
AP	Injectable H20 Solutions - OK	Injectable aqueous solutions
AT	Topical products - OK	Topical products
A1	Bioequivalence Resolved	Equivalent to <i>Orange Book</i> value of "AB1".  Products with this code are only equivalent to other products with the same GPI and the same TEE Code.
A2	Bioequivalence Resolved	Equivalent to <i>Orange Book</i> value of "AB2".  Products with this code are only equivalent to other products with the same GPI and the same TEE Code.
A3	Bioequivalence Resolved	Equivalent to <i>Orange Book</i> value of "AB3".  Products with this code are only equivalent to other products with the same GPI and the same TEE Code.

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Code	Description	Definition
A4	Bioequivalence Resolved	Equivalent to <i>Orange Book</i> value of "AB4".  Products with this code are only equivalent to other products with the same GPI and the same TEE Code.
BC	CRTB/CRCP/CR - INJS Problems	Controlled-release dosage forms
BD	Al or DF Documented Problems	Ingredients and dosage forms with documented bioequivalence problems
BE	ECTB Oral Problems	Enteric-coated oral dosage forms
BN	Aerosol - Nebulizer Problems	Products in aerosol-nebulizer drug delivery systems
BP	Al or DF Potential Problems	Active ingredients and dosage forms with potential bioequivalence problems (for example, injectable suspensions)
BR	Supp/Enem Systemic Problems	Suppositories or enemas for systemic use
BS	Drug Standard Problems	Products having drug standard deficiencies
BT	Topical Problems	Topical products with bioequivalence issues
ВХ	Insufficient Data	Drug products for which data are insufficient to determine therapeutic equivalence
B*	Requires Further Investigation	Products requiring further FDA investigation to determine therapeutic equivalence
NA	Not Available	Information is not available
NR	Not Rated	Drug product has not yet been rated

## Note

TEE Codes beginning with "A" (except values of "A1", "A2", "A3" and "A4") indicate drug products that are therapeutically equivalent to other pharmaceutically equivalent products. Products with an "A" TEE Code are generally considered interchangeable with pharmaceutically equivalent drug products, subject to individual state regulations governing product substitution. In the exception noted above, the full two-character TEE Code is necessary to find therapeutically equivalent drugs (such as when comparing a GPI category containing both "A1", "A2", "A3" and "A4" ratings).

If the FDA uses TEE Codes greater than AB4, such as AB5, then similar two-character codes may be adopted by Wolters Kluwer Clinical Drug Information.

In the case where multiple TEE Codes apply to a product, MED-File v2 will only output one value. For example, a product may have both AB1 and AB2 listings in the Orange Book, but MDDB will show only one value and will represent this as 'AB'.

TEE Codes beginning with "B" indicate drug products that the FDA does not consider therapeutically equivalent to other pharmaceutically equivalent drug products. These products are generally prohibited from product substitution by state laws.

The Bioequivalence Code which is a summarization of the TEE Code is assigned to a DDID.

## **Drug Product Substitution**

Although FDA guidelines are nationally recognized, specific laws and regulations governing drug product selection are established and enforced by individual states. Therefore, interpreting and applying TEE Codes are the responsibility of the end-user.

## **Third-Party Restriction Code**

The Third-Party Restriction Code is a proprietary Wolters Kluwer Clinical Drug Information concept assigned to the NDC-UPC-HRI that provides generalized groupings of drug products. The information may be used by Third Party Administrators (TPAs) or others to identify drug products for formulary inclusion or exclusion. This information is provided as a general guideline to follow.

#### Current values are:

Description	Definition
Insulin	
Oral Contraceptives	
Surgical Supply/Medical Device/Ostomy	
Blood Component	
Diagnostic Agent	
General Anesthetic	
Fertility Drugs	
Anorexic, Anti-obesity	
Multiple Vitamin	Single-ingredient vitamins can be selected using the Generic Product Identifier (Data Element Code K075)
Used for HIV Infection	
Bulk Chemicals	
Cosmetic Alteration Drugs	Does not include acne agents
Antidepressants	
Multiple Vitamin with	
Fluoride	
Growth Hormones/ Biosynthetic Hormones	

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Description	Definition
Hypnotics/Sedatives	
Multiple Vitamin with Iron	Single-ingredient or other iron products not combined with multiple vitamins can be selected by using the Generic Product Identifier (Data Element Code K075)
Non Oral Systemic	TD patches, injectables, implants, IUDs
Contraceptives	
Contraceptives Other	Condoms, diaphragms, spermacides
Immunosuppressants	
Antipsychotics	
Smoking Deterrents	
Antianxiety Agents	
Impotence Agents	Sildenafil, yohimbine
Not Applicable	

The Third Party Code assigned to an NDC-UPC-HRI can change over time. The change could be the result of:

- Drug Indication change: If it can be determined that the primary use of a drug has changed over time, then the Third Party Restriction Code may change as a result.
- More drug information becomes available: If more information or clarification about the drug and/or its use becomes available, then the Third Party Restriction Code may change.
- **GPI Change to a product**: A change to the product's GPI may cause the Third Party Restriction Code to change. This may be the result of incorrect or updated information from the labeler, for example, that may cause the product's GPI to change.

# **Chapter 3: MED-File v2 Database Structure**

# In This Chapter

Understanding the Database Structure Filenames Database Layout Reserve Fields File Relationships

# **Understanding the Database Structure**

Wolters Kluwer Clinical Drug Information data is organized into multiple files. The files reflect the following information.

Note

This information is grouped in categories, not how it appears on the media.

# **Copyright Information**

A Copyright File is supplied to indicate Wolters Kluwer Clinical Drug Information's copyright position.

# Marketing/General Technical Information

A ReadMe File is supplied to keep you abreast of the latest news and general technical information.

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## **Database Control Information**

A series of files is supplied with each database to provide information about the database.

- Summary File containing Issue Date, Expiration Date, Volume, and other descriptive information about the database
- Data Dictionary File identifying all the fields that are contained in each of the database-specific files
- Validation/Translation File containing the possible values for fields where applicable

## **Database-Specific Information**

Each database has one or more files containing the database's detailed data contents. The data are split across files to allow relational processing of the data.

Database files are available through file transfer protocol (FTP), and through our Web site, wds.medispan.com.

# **Filenames**

MED-File v2 is available in four file combinations:

- Basic
- Clinical
- Complete
- Pricing

The table on the next page displays the files associated with each option of MFD-File v2.

Table 3-1: MED-File v2 Filenames and Options

Category	File Description	Filename	Basic	Clinical	Pricing	Complete
Copyright Information	Copyright File	MF2COPY	X	X	X	X
Marketing/General Technical Information	ReadMe File	MF2READ	X	X	X	X
Database Control Information	Summary File	MF2SUM	X	X	X	X
	Data Dictionary File	MF2DICT	X	X	X	X
	Validation/Translation File	MF2VAL	X	X	X	X
Database-Specific Information	Drug Name File	MF2NAME	X	X	X	X
	TC-GPI Name File	MF2TCGPI	X	X	X	X
	NDC File	MF2NDC	X	X	X	X
	Labeler File	MF2LAB	X	X	X	X
	GPPC File	MF2GPPC	X	X	X	X
	Error Correct File*	MF2ERR	X	X	X	X
	GPPC Price File	MF2GPR			X	X
	NDC Price File	MF2PRC			X	X
	Modifier File	MF2MOD			X	X
	NDC Modifier File	MF2NDCM			X	X
	SDI Drug Name File	MF2DRGNM		X		X
	Routed Drug File	MF2RTDRG		X		X
	Drug-Dose Form File	MF2DFDRG		X		X
	Routed Drug Form File	MF2RTDF		X		X
	Dispensable Drug File	MF2DRG		X		X
	Description File	MF2DESC		X		X
	Route File	MF2RTE		X		X

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Category	File Description	Filename	Basic	Clinical	Pricing	Complete
Database-Specific Information,	Dose Form File	MF2FRM		X		X
continued	Strength-Strength Unit of Measure File	MF2STUOM		X		X
	Drug Concept ID to Ingredient Set ID File	MF2SET		X		X
	Ingredient Set ID to Ingredient ID File	MF2INGS		X		X
	Ingredient ID to Drug-Strength File	MF2STR		X		X
	Ingredient Drug File	MF2IDRG		X		X
	Secondary Alternate ID File	MF2SEC	X	X	X	X
	Reference Name File	MF2RNM		X		X

Note * The Error Correct File is present only in an Incremental Update when an error has been made.				
Note	In the future, files may be added to provide information to meet the new needs of end-users.			

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# **Database Layout**

The following information is given for each field in MED-File v2:

## **Data Element Name**

The full name of the field.

## **Data Element Code**

A code identifying the record and position of the field within the file.

## Field Validation

A flag indicating if values are available in the Validation/Translation File. Wolters Kluwer Clinical Drug Information reserves the right to add values and descriptions for the field.

Note

The Validation/Translation File contains a list of the most current values for the fields.

## **Record Position**

The beginning and ending location in the file for the field.

# Length/Type

The number used to indicate the type and length of the field. For example, 10/N indicates that the field is a 10-digit number. Wolters Kluwer Clinical Drug Information defines data as either character or numeric.

#### C = Character

The values for the field contain alphabetic letters, numbers, symbols, or blanks. The field is left-justified. Records without a value for the field will be blank.

#### N = Numeric

The values for the field contain numbers or zeros. The values for the field are right-justified or justified at the decimal point. Dates are not distinguished from other numeric fields.

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## **Picture**

The COBOL programming representation of the field. The representation includes the length of the field and the type of data. For numeric fields with decimal points, this representation will indicate the location of the fixed decimal point. The values used in the picture are:

Value	Description
9	Numeric digit
X	Character (alphanumeric, including alphabetic)
V	Implied decimal point

## Examples:

Picture	Received As	Interpreted
9(5)V9(3)	12345123	12345.123
9(6)	123456	123456.
X(5)	XXXXX	XXXXX

# Last Change Date

The date of the last change made to the field.

# **Data Element Description**

A brief description of the field.

Note	A "b" indicates a blank within a field.  Although different programming languages use different representations, the fields remain the same. Wolters Kluwer Clinical Drug Information's database layouts are flexible and not restricted to any particular programming language.		
Note			
Note	Detailed field information is only given for fields that appear in the MED-File v2 Data Dictionary File. Some standard files (such as Summary, ReadMe, and Copyright) do not have fields listed in the Data Dictionary File, so only a general discussion of these fields is provided.		

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# Reserve Fields

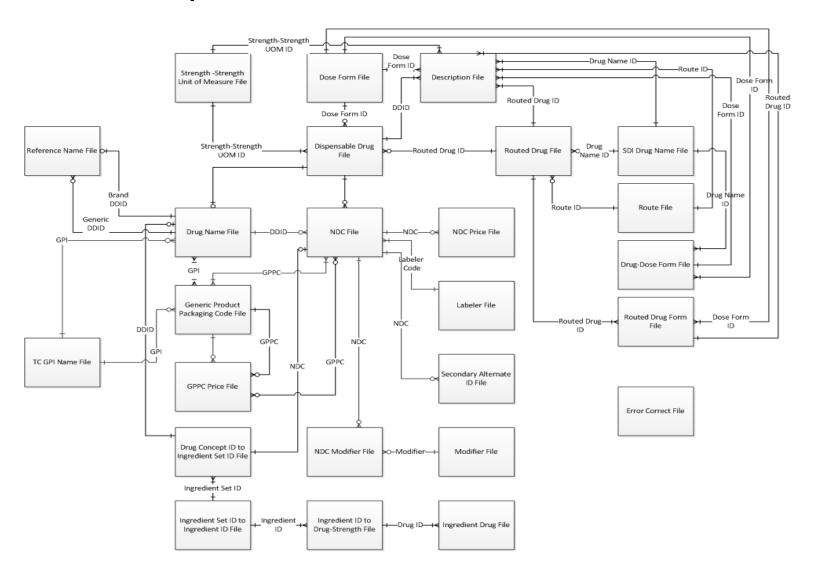
Fields marked as "Reserve" may be used by Wolters Kluwer Clinical Drug Information in the future for additional data fields.

Do not assume fields will always be blank. Do not validate these fields during a load. You should ignore all reserve fields.

When we require you to use a reserve field, we will notify you or the end-user with that information.

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# **File Relationships**



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# **Chapter 4: MED-File v2 Data Elements**

# In This Chapter...

Copyright File

ReadMe File

Data Dictionary File

Validation/Translation File

Summary File

Drug Name File

TC-GPI Name File

NDC File

Labeler File

**GPPC File** 

**Error Correct File** 

**GPPC Price File** 

NDC Price File

**Modifier File** 

NDC Modifier File

SDI Drug Name File

Routed Drug File

Drug-Dose Form File

Routed Drug Form File

Dispensable Drug File

**Description File** 

Route File

Dose Form File

Strength-Strength Unit of Measure File

Drug Concept ID to Ingredient Set ID File

Ingredient Set ID to Ingredient ID File

Ingredient ID to Drug-Strength File

Ingredient Drug File

Secondary Alternate ID File

Reference Name File

# **Copyright File**

## (MF2COPY)

The Copyright File is one record containing the Clinical Drug Information, LLC copyright statement.

Data Element Name	Record Position	Type/Length	Picture
Clinical Drug Information, LLC	1-55	C/55	X(55)
Copyright Statement			

# ReadMe File

## (MF2READ)

The ReadMe File is a text file that can include the following:

- new release information
- reminders of upcoming changes
- technical information of interest

#### Note

Programming for specific values in the ReadMe File is discouraged. The text line is 80 characters for easy printing; however, the content, style, and layout may change without notice. Wolters Kluwer Clinical Drug Information reserves the right to change the format of the information provided in the ReadMe File, but advance notice will be given prior to any changes in field lengths in this file.

Code	Data Element Name	Record Position	Type/Length	Picture
B001	ReadMe Text Line	1-80	C/80	X(80)

# **Data Dictionary File**

## (MF2DICT)

The Data Dictionary File includes data definitions used to generate the physical description of the database files and the remaining files supplied with the offering.

The Data Dictionary File contains the following data elements:

Code	Data Element Name	Record Position	Type/Length	Picture
C001	Field Identifier	1-4	C/4	X(4)
C005	Field Description	5-39	C/35	X(35)

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Code	Data Element Name	Record Position	Type/Length	Picture
C040	Field Type	40-40	C/1	Х
C041	Field Length	41-43	N/3	9(3)
C044	Implied Decimal Flag	44-44	C/1	Х
C045	Decimal Places	45-46	N/2	9(2)
C047	Field Validation Flag	47-47	C/1	Х
C048	Field Abbreviation	48-48	C/1	Х
	Flag			
C049	Reserve	49-64	C/16	X(16)

<b>Note</b> The shaded row represents the unique key into the file.	
---	--

## **Field Identifier**

This is a 4-character field.

The Field Identifier specifies the field within the offering by Data Element Code.

Field Identifier Field Description		Field Type	Field Length
F039 Dosage Form		С	4
H022 RX-OTC Indicator Code		С	2
L010 Effective Date		N	8
Q008	Concept ID	N	10

# **Field Description**

This is a 35-character field.

The Field Description contains the Data Element Name of the field. This field is mixed case and may be abbreviated to fit into the 35 bytes of space allotted.

Field Identifier	Field Description	Field Type	Field Length
F039	Dosage Form	С	4
H022	RX-OTC Indicator Code	С	2
L010	Effective Date	N	8
Q008	Concept ID	N	10

# Field Type

This is a 1-character field.

The Field Type defines the type of field allowing for automated record layout or table definition.

## Valid Values:

Code	Description
С	Character
N	Number

## Example

Field Identifier	Field Description	Field Type	Field Length
F039	Dosage Form	С	4
H022	RX-OTC Indicator Code	С	2
L010	Effective Date	N	8
Q008	Concept ID	N	10

# **Field Length**

This is a 3-numeric field.

The Field Length specifies the number of positions representing the data value within the record.

Field Identifier	Field Description	Field Type	Field Length
F039	Dosage Form	С	4
H022	RX-OTC Indicator Code	С	2
L010	Effective Date	N	8
Q008	Concept ID	N	10

# **Implied Decimal Flag**

This is a 1-character field.

The Implied Decimal Flag indicates an implied decimal in the field.

## Valid Values:

Cod	е	Description
Υ		Yes, the field has an implied decimal
N		No, the field does not have an implied decimal

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Note	If the Field Type [Data Element Code C040] is "C", this field will always be
	"N".

## Example:

Value	Picture	Field Type	Field Length	Implied Decimal	Decimal Places
12.34	9(2)V9(2)	N	4	Υ	02
12345.1234	9(5)V9(4)	N	9	Υ	04
1234	9(4)	N	4	N	00
ABC	X(3)	С	3	N	00

## **Decimal Places**

This is a 2-numeric field.

The Decimal Places field shows the number of implied decimal positions in a value if the Implied Decimal Flag [Data Element Code C044] is "Y".

## Example:

Value	Picture	Field Type	Field Length	Implied Decimal	Decimal Places
12.34	9(2)V9(2)	N	4	Υ	02
12345.1234	9(5)V9(4)	N	9	Υ	04
1234	9(4)	N	4	N	00
ABC	X(3)	С	3	N	00

# **Field Validation Flag**

This is a 1-character field.

The Field Validation Flag indicates if the field has associated values in the Validation/Translation File.

#### Valid Values:

Flag	Description
Υ	Yes, the field has associated validation values in the Validation/Translation File.
N	No, the field does not have associated validation values in the Validation/Translation File.

# **Field Abbreviation Flag**

This is a 1-character field.

The Field Abbreviation Flag indicates if the field has associated abbreviation values in the Validation/Translation File.

## Valid Values:

Flag	Description
Υ	Yes, the field has an associated abbreviation field in the Validation/Translation File.
N	No, the field does not have an associated abbreviation field in the Validation/Translation File.

## Reserve

This is a 16-character field.

The Reserve field is an unused field that may be used at a future date.

# Validation/Translation File

## (MF2VAL)

The Validation/Translation File allows you to design programs that

- validate values and their descriptions for a field
- create pick lists for end-user input
- · create alternate values for a field

Using this file makes systems and programs more flexible and easier to maintain. Its use is encouraged in system design. The Validation/Translation File may contain new values for a field without advance notice; therefore, hard coding values is not recommended.

4-6 MED-File v2 Published: 11/11 Revised: 04/18 The Validation/Translation File contains the following data elements:

Code	Name	Record Position	Type/Length	Picture
D001	Field Identifier	1-4	C/4	X(4)
D005	Field Value	5-19	C/15	X(15)
D020	Language Code	20-21	N/2	9(2)
D022	Value Description	22-61	C/40	X(40)
D062	Value Abbreviation	62-76	C/15	X(15)
D077	Reserve	77-96	C/20	X(20)

**Note** The shaded rows represent the unique key into the file.

## **Field Identifier**

This is a 4-character field.

The Field Identifier specifies the field within the offering by Data Element Code.

## Example:

Field Identifier	Field Value	Language Code	Value Description	Value Abbreviation
F037	IJ	01	Injection	
F039	CPCR	01	Capsule Extended Release	Capsule ER
F069	1	01	No accepted medical use	C-I
H082	3	01	Ranked between 201 and 300	

## **Field Value**

This is a 15-character field.

The Field Value contains the values for the Field Identifier [Data Element Code D001].

## Example:

Field Identifier	Field Value	Language Code	Value Description	Value Abbreviation
F037	IJ	01	Injection	
F039	CPCR	01	Capsule Extended Release	Capsule ER
F069	1	01	No accepted medical use	C-I
H082	3	01	Ranked between 201 and 300	

# **Language Code**

This is a 2-numeric field.

The Language Code indicates in which language the Value Description and Value Abbreviation are expressed.

## Valid Values:

Code	Language
01	English

## Example:

Field Identifier	Field Value	Language Code	Value Description	Value Abbreviation
F037	IJ	01	Injection	
F039	CPCR	01	Capsule Extended Release	Capsule ER
F069	1	01	No accepted medical use	C-I
H082	3	01	Ranked between 201 and 300	

# **Value Description**

This is a 40-character field.

The Value Description provides an interpretation of the Field Value [Data Element Code D005].

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## Example:

Field Identifier	Field Value	Language Code	Value Description	Value Abbreviation
F037	IJ	01	Injection	
F039	CPCR	01	Capsule Extended Release	Capsule ER
F069	1	01	No accepted medical use	C-I
H082	3	01	Ranked between 201 and 300	

## Note

The Field Value is not intended for presentation to end-users. To minimize errors and confusion, end-users should be presented with the Value Description. Use of the Value Abbreviation is also discouraged. This applies to all aspects of your application including drop-down lists and field displays in the user interface as well as documents and other printed reports.

## **Value Abbreviation**

This is a 15-character field.

The Value Abbreviation is a field used for abbreviated Value Descriptions [Data Element Code D022].

## Example:

Field Identifier	Field Value	Language Code	Value Description	Value Abbreviation
F037	IJ	01	Injection	
F039	CPCR	01	Capsule Extended Release	Capsule ER
F069	1	01	No accepted medical use	C-I
H082	3	01	Ranked between 201 and 300	

## Reserve

This is a 20-character field.

The Reserve field is an unused field that may be used at a future date.

# **Summary File**

## (MF2SUM)

The Summary File provides specific information for use and reference during loading or updating processes. It allows you to check that you have received the proper offering, are using the appropriate update technique, and have not missed updates.

The format of the Summary File allows for easy viewing and printing during loading and verification.

To ensure the proper sequence of updates, a Volume Number and Supplement Number are included. When applicable, Locality Information (country and language identification) is supplied. The Summary File includes

- copyright information
- identification by Database Name
- product issue information (including the Version Number, Volume Number, Create Date, Issue Date, Expiration Date, and Kill Date)
- the File Mode (Production or Test)
- the File Type (incremental update or full replacement database)
- a Table of Contents (listing filenames, location of files, number of files, file sizes, and number of records in each file)

Note	This file is supplied in its entirety regardless of the type of database
	ordered.

Code	Data Element Name	Record Position	Type/Length	Picture
A001	Record Type	1-3	C/3	X(3)
A004	Reserve 1	4-4	C/1	Х
A005	Sequence Number	5-7	N/3	9(3)
A008	Reserve 2	8-8	C/1	Х
A009	Comment Marker	9-9	C/1	Х
A010	Data or Comment	10-96	C/87	X(87)*

\* The length for records within the Summary File is not fixed, and may vary from row to row; however, it will not exceed the value noted in the table above.

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# **Drug Name File**

## (MF2NAME)

The Drug Name File provides the primary product name used to identify groups of drug and health-related items. It also contains many attributes of the drug name and provides keys to access several of Wolters Kluwer Clinical Drug Information's clinical database offerings.

Note	The values listed here are generalized to the drug name level. If you need to
	know the values of a particular drug item, refer to the "NDC File".

The Drug Name File contains the following data elements:

Code	Data Element Name	Record Position	Type/Length	Picture
F001	Drug Descriptor Identifier	1-6	N/6	9(6)
F007	Drug Name	7-36	C/30	X(30)
F037	Route of Administration Code	37-38	C/2	X(2)
F039	Dosage Form	39-42	C/4	X(4)
F043	Strength	43-57	C/15	X(15)
F058	Strength Unit-of-Measure	58-67	C/10	X(10)
F068	Bioequivalence Code	68-68	C/1	Х
F069	Controlled Substance Code	69-69	C/1	Х
F070	Efficacy Code	70-70	C/1	Х
F071	Legend Indicator Code	71-71	C/1	Х
F072	Multi-Source Summary Code	72-72	C/1	Х
F073	Brand Name Code	73-73	C/1	Х
F074	Name Source Code	74-74	C/1	Х
F075	Generic Product Identifier	75-88	C/14	X(14)
F089	Knowledge Base Drug Code	89-98	N/10	9(10)
F099	New Drug Descriptor Identifier	99-104	N/6	9(6)
F105	Screenable Flag	105-105	C/1	Х
F106	KDC Flag	106-106	C/1	Х
F107	Local/Systemic Code	107-107	C/1	X
F108	Maintenance Drug Code	108-108	C/1	Х
F109	Form Type Code	109-109	C/1	Х
F110	Internal-External Code	110-110	C/1	Х

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Code	Data Element Name	Record Position	Type/Length	Picture
F111	Single-Combination Code	111-111	C/1	Х
F112	Representative GPI Flag	112-112	C/1	Х
F113	Representative KDC Flag	113-113	C/1	Х
F114	Reserve	114-119	C/6	X(6)
F120	Transaction CD	120-120	C/1	Х
F121	Last Change Date	121-128	N/8	9(8)

**Note** The shaded row represents the unique key into the file.

# **Drug Descriptor Identifier**

This is a 6-digit numeric field.

The Drug Descriptor Identifier (DDID) is a six-digit number that identifies a unique combination of Drug Name, Route, Dosage Form, Strength, and Strength Unit of Measure. The value of the identifier itself has no meaning. It is used to identify a unique drug product with respect to these fields alone. It does not distinguish drug products by Package Size, TEE Code, DESI Code, DEA Class Code, Brand Name, GPI, or Multi-Source Summary Code.

This code is associated to the NDC File in a one-to-many relationship.

The Drug Descriptor Identifier and Dispensable Drug Identifier are one and the same, and may be used interchangeably in this and other Wolters Kluwer Clinical Drug Information documentation. For more information, go to Drug Descriptor Identifier in Chapter 2, "Editorial Policies".

## Example:

Drug	Drug Name	Route	Dosage	Strength	SUM
Descriptor ID			Form		
001847	Artificial Tears	OP	OINT		
023426	VinCRIStine Sulfate	IV	SOLN	1	MG/ML
032186	Diltiazem HCI CR	PO	CP12	120	MG
088732	Vytorin	PO	TABS	10-10	MG
089216	HalfLytely Bowel Prep	PO	KIT	5-210	MG-GM

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# **Drug Name**

This is a 30-character field.

The Drug Name field reflects the product name shown by the manufacturer on the package. This 30-character name is depicted in upper and lower case. Some drug names are represented using Tall Man letters to distinguish similar drug names and reduce the potential for medication errors. Tall Man letters should be maintained and are not to be changed within your application. An example of drug names with Tall Man letters are VinCRIStine Sulfate and VinBLAStine Sulfate.

For more information, see "Drug Name" in Chapter 2.

## Example:

Drug Descriptor ID	Drug Name	Route	Dosage Form	Strength	SUM
001847	Artificial Tears	OP	OINT		
023426	VinCRIStine Sulfate	IV	SOLN	1	MG/ML
032186	Diltiazem HCI CR	PO	CP12	120	MG
088732	Vytorin	PO	TABS	10-10	MG
089216	HalfLytely Bowel Prep	РО	KIT	5-210	MG-GM

## **Route Of Administration Code**

This is a 2-character field.

The Route of Administration Code defines the route of the drug based on the packaging. This route may not represent the clinical route by which the drug is ultimately given to a patient.

**Note** The Comment column in the table below is for information purposes only. Its contents are not included in the Validation/Translation File.

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#### Note

The 2-character Route of Administration Code is not to be displayed or provided in print form in end-user applications. The code should be translated to its corresponding Value Description as defined in the Validation/Translation File. Significant patient safety issues are associated with the use of non-standard abbreviations such as those found in the Route of Administration Code.

## Example

Drug Descriptor ID	Drug Name	Route	Dosage Form	Strength	SUM
001847	Artificial Tears	OP	OINT		
023426	VinCRIStine Sulfate	IV	SOLN	1	MG/ML
032186	Diltiazem HCI CR	РО	CP12	120	MG
088732	Vytorin	PO	TABS	10-10	MG
089216	HalfLytely Bowel Prep	РО	KIT	5-210	MG-GM

## The current values are:

Route	Code	Description
BUCCAL	BU	Administered inside the mouth on the mucosa of the cheek
COMBINATION	СО	More than one route, excluding route combinations that only include injectable sites
DENTAL	DT	Application to teeth or gums
DOES NOT APPLY	XX	Use of a route does not apply
ENTERAL	EN	Administered directly into the gastrointestinal tract when the oral route cannot be used (i.e. tube feedings). This route is reserved for commercially available products that are exclusively administered this way.
EPIDURAL*	EP	Injection upon or outside of the dura mater
EXTERNAL	EX	Applied externally to the skin or hair
EXTRACORPOREAL	EC	A procedure that takes place outside the body (i.e. photopheresis, plasmapheresis).
HEMODIALYSIS	HM	A process of removing wastes and toxins from the blood. Products having this route are used in the hemodialysis process or added to the hemodialysate as part of the process.

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Route	Code	Description
IMPLANT	IL	Placing a drug form, drug delivery device, or other
		device at the desired administration site by insertion
		into a body tissue or body cavity by surgical or other
		appropriate insertion procedures
IN VITRO	VI	Not taken internally or applied externally to a
		patient's body
INHALATION	IN	Drug administration into the lungs (either during a
		drawn or forced breath)
INJECTION	IJ	A set of one or more injectable routes or the route of
		injection is not specified
INTRA-ARTERIAL*	IA	Injection into an artery or intra-arterial port
INTRA-ARTICULAR*	IX	Injection into a joint
INTRACARDIAC	CA	Administered directly to one of the chambers of the
		heart.
INTRACAVERNOSAL*	IC	Injection into the corpora cavernosa
INTRACAVITARY	CV	Insertion into a body cavity.
INTRADERMAL*	ID	Injection within the epidermis (skin)
INTRALESIONAL	LS	Administered directly into a lesion.
INTRAMUSCULAR*	IM	Injection into a muscle group
INTRAOCULAR	Ю	Injection, implantation or surgical irrigation within the
		eyeball
INTRAPERITONEAL	IP	Administration into the intraperitoneal cavity
		commonly by injection or instillation into an intraperitoneal catheter port
INTRAPLEURAL	PL	Administration into the pleura or pleural cavity.
INTRASINAL	SN	Administration into the pleura of pleura cavity.  Administration of a substance within the nasal or
INTRASINAL	SIN	periorbital sinuses.
INTRATHECAL*	IT	Injection into a subarachnoid or subdural space
INTRATRACHEAL	TR	Administered through the trachea (i.e. via
INTIONITONOTIENE		endotracheal tube or percutaneous injection).
INTRATYMPANIC	TP	Administration of a substance directly into the tympanic
		cavity.
INTRAUTERINE	IU	Administered within the uterus
INTRAVENOUS*	IV	Injection directly into a vein or into a venous line port
INTRAVESICAL	IS	Administered into the bladder
INTRAVITREAL	IZ	Administered directly to the vitreous body within the
		eye.
IONTOPHORESIS	PH	Administration of a drug through the skin driven by an
		electric field.
IRRIGATION	IR	To flush a body cavity or site with a stream of liquid
MOUTH/THROAT	MT	Applied to a mucous membrane of the oral cavity or throat
NASAL	NA	Administered via the nose
INASAL	INA	Auministered via the mose

Route	Code	Description
OPHTHALMIC	OP	Administered onto the surface of the eyeball or into
		the conjunctival sac
ORAL	PO	Taken by mouth
OTIC	OT	Commonly administered into the external ear canal
PERFUSION	PF	Administration (pumping) of a fluid through an organ or tissue
RECTAL	PR	Administered into the rectum (in the anal canal beyond the anal sphincter)
SUBCUTANEOUS*	SC	Injection through the skin into the loose subcutaneous tissue under the skin
SUBLINGUAL	SL	Administered under the tongue
TRANSDERMAL	TD	Applied topically (e.g., patch or ointment) with absorption through the skin for systemic effect
TRANSLINGUAL	TL	Drug absorption through the tongue into systemic circulation after application on the tongue
TRANSMUCOSAL	TM	Administration through or across a mucous membrane.
URETHRAL	UR	Administered via insertion or instillation into the uretha
VAGINAL	VA	Administered into the vagina

<sup>\*</sup> These Codes are used for drug products limited to this particular route. If more than one route of injection is applicable or if the route of injection is not specified, Wolters Kluwer Clinical Drug Information will assign a route of "IJ".

# **Dosage Form Code**

This is a 4-character field.

Abbreviation.

The Dosage Form Code indicates the form in which the drug product is dispensed.

Note	The 4-character Dosage Form Code is not to be displayed or provided in
	print form in end-user applications. The code should be translated to its
	corresponding Value Description as defined in the Validation/Translation
	File. Use of the Value Abbreviation is also discouraged. Significant patient
	safety issues are associated with the use of non-standard abbreviations such
	as those found in the Dosage Form Code and its corresponding Value

For a complete list of their current values, go to Appendix D, "Dosage Form Codes".

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# Example:

Drug Descriptor ID	Drug Name	Route	Dosage Form	Strength	SUM
•			1 01111		
001847	Artificial Tears	OP	OINT		
023426	VinCRIStine	IV	SOLN	1	MG/ML
	Sulfate				
032186	Diltiazem HCI	PO	CP12	120	MG
	CR				
088732	Vytorin	PO	TABS	10-10	MG
089216	HalfLytely	PO	KIT	5-210	MG-GM
	Bowel Prep				

# Strength

This is a 15-character field.

The Strength is a character representation of the product's ingredient strength. When combined with the Strength Unit of Measure, it represents the dosage strength as provided by the manufacturer.

### Example:

Drug Descriptor ID	Drug Name	Route	Dosage Form	Strength	SUM
001847	Artificial Tears	OP	OINT		
023426	VinCRIStine Sulfate	IV	SOLN	1	MG/ML
032186	Diltiazem HCI CR	PO	CP12	120	MG
088732	Vytorin	PO	TABS	10-10	MG
089216	HalfLytely Bowel Prep	РО	KIT	5-210	MG-GM

# **Strength Unit Of Measure**

This is a 10-character field.

The Strength Unit of Measure (SUM), when combined with the Strength, represents the dosage strength as provided by the manufacturer.

### Valid Values:\*

Strength	Description	Strength	Description
%	Percent	MG	Milligram
AHFU	Antihemophilic factor unit	MG/HR	Milligram/hour
GM	Gram	MG/ML	Milligram/milliliter
GM/ML	Gram/milliliter	MINIM	Minim
UNIT	International unit	MMOLE	Millimole
UNIT/ML	International unit/ milliliter	MMOLE/ML	Millimole/milliliter
MCG	Microgram	MU	Million units
MCG/ML	Microgram/milliliter	SQ CM	Square centimeter
MEQ	Milliequivalent	UNIT	Unit
MEQ/L	Milliequivalent/liter	UNIT/GM	Unit/gram
MEQ/ML	Milliequivalent/ milliliter	UNIT/ML	Unit/milliliter

## Example:

Drug Descriptor ID	Drug Name	Route	Dosage Form	Strength	SUM
001847	Artificial Tears	OP	OINT		
023426	VinCRIStine Sulfate	IV	SOLN	1	MG/ML
032186	Diltiazem HCI CR	PO	CP12	120	MG
088732	Vytorin	PO	TABS	10-10	MG
089216	HalfLytely Bowel Prep	РО	KIT	5-210	MG-GM

Note \* Due to the dynamic nature of these data, additional values may be added without notice.

# **Bioequivalence Code**

This is a 1-character field.

The Bioequivalence Code is a generalization of the Therapeutic Equivalence Evaluation (TEE) Code for products sharing a DDID. This code also indicates

4-18 MED-File v2 Published: 11/11 Revised: 04/18 when the TEE Code cannot be generalized. For instance, the Bioequivalence Code will be set to "C" in this field

- if two different packaged drug products (different NDC-UPC-HRI codes but sharing the same DDID) have different TEE Codes (for example: "A1" and "A2")
- when multiple TEE Codes exist for a DDID

#### Valid Values:

Value	Description	
Α	Products in same GPI are equivalent	
В	Products in same GPI are not equivalent	
С	Products may or may not be equivalent	
N	Equivalency determination not available	
U	Undeterminable (obsolete)	

### **Controlled Substance Code**

This is a 1-character field.

The Controlled Substance Code identifies federally controlled substances, as classified by the Drug Enforcement Administration (DEA). The DEA Class Code [Data Element Code H020] is specific for an NDC-UPC-HRI. Here, the Controlled Substance Code is a general DEA Class Code for all products sharing a DDID and is determined by the DEA Class Code for the NDCs in the NDC File (MF2NDC). If more than one code is possible for a DDID, the value of "U" will appear in this field.

#### Valid Values:

Value	Description	Definition	Abbrev
1	No accepted medical use	High abuse potential; medical use not accepted (such as heroin, marijuana, and LSD)	C-I
2	High abuse, severe dependence liability	High abuse potential with severe dependence liability (such as narcotics, amphetamines, and barbiturates)	C-II

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Value	Description	Definition	Abbrev
3	Moderate dependence liability	Less abuse potential than Schedule II drugs and moderate dependence liability (such as nonbarbiturate sedatives, nonamphetamine stimulants, and limited amounts of certain narcotics)	C-III
4	Limited abuse potential	Less abuse potential than Schedule III drugs and limited dependence liability (such as some sedatives, antianxiety agents, and non-narcotic analgesics)	C-IV
5	Limited abuse potential, small amounts	Limited abuse potential; primarily small amounts of narcotics (codeine) used as antitussives or antidiarrheals; under federal law, limited quantities of certain C-V drugs may be purchased directly from a pharmacist without a prescription; can be either prescription or OTC	C-V
b⁄	DEA Class Code is not applicable	A DEA Class Code is not applicable	N/A
U	Undeterminable	A DEA Class Code is undeterminable	Undet

# **Efficacy Code**

This is a 1-character field.

The Efficacy Code identifies the stage of review for drugs pending final resolutions of efficacy by the FDA's Drug Efficacy Study Implementation (DESI) program. The DESI Code [Data Element Code H021] is specific for an NDC-UPC-HRI. Here, the Efficacy Code is a general DESI Code for all products sharing a DDID and is determined by the DESI Code for the NDCs in the NDC File (MF2NDC). If more than one code is possible for a DDID, the value of "U" will appear in this field.

According to the FDA, the following codes are valid. Additionally, Wolters Kluwer Clinical Drug Information includes the value of "b" (blank) for non-drug and other non-applicable items.

#### Valid Values:

Value	Description	Definition
p,	Non-drug and other non- applicable items	Non-drug and other non-applicable items
	applicable items	items
2	Determined to be safe and	Non-DESI/IRS drugs or DESI/IRS drugs
	effective	determined to be safe and effective
3	Under review (NOOH has not been issued)	DESI/IRS drugs under review (NOOH has not been issued)

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Value	Description	Definition
4	Less than effective for some	LTE DESI/IRS drugs for some
	indications	indications
5	Less than effective for all indications	LTE DESI/IRS drugs for all indications
6	Less than effective, withdrawn	LTE DESI/IRS drugs withdrawn from the market
U	Undeterminable	An Efficacy Code is undeterminable

# **Legend Indicator Code**

This is a 1-character field.

The Legend Indicator Code indicates Federal Prescription (legend) or Over-the-Counter (OTC) (non-legend) status. If coded "R", the item requires a prescription; if coded "O", the item is an OTC product. The Legend Indicator Code is a general RX-OTC Indicator Code for all products sharing a DDID and is determined by the RX-OTC Indicator Code for NDCs in the NDC File (MF2NDC). If more than one code is possible for a DDID, the value of "U" will appear in this field.

#### Valid Values:

Value	Description
0	OTC
R	Rx
U	Undeterminable (Both Rx and OTC)

# **Multi-Source Summary Code**

This is a 1-character field.

The Multi-Source Summary Code identifies drug products as either single- or multiple-source original drug products or a generic copy of the standard drug product. This code is provided by Wolters Kluwer Clinical Drug Information as a general guideline. The drug product price may be needed as a determining factor for generic substitution.

#### Valid Values:

Value	Description	Definition
N	Single-source product	Single-source product available from one labeler.
M	Single-source, co-licensed product	Product is co-licensed and considered a single-source product despite being available from multiple labelers.
0	Multi-source, originator product	Product available from multiple labelers considered to be the industry standard.
Υ	Multi-source product	Multi-source product available from multiple labelers.

Note	Products are designated "N" when the Multi-Source Code does not apply. For
	example, medical devices, partial GPIs, biologicals, and prenatal vitamins.

## Example:

Condition	N	M	0	Υ
Single-Source	Lantus Inj	-	-	-
Co-license	-	Adderal XR Oral Capsule Extended Release 24 Hour 10 MG AND Amphetamine- Dextroamphetamine Oral Capsule Extended Release 24 Hour 10 MG	-	-
Original with	-	-	Valium 5	Diazepam
Generics			mg	5 mg
Former Co- licensing with	-	-	Septra DS	SMZ/TMP DS
Generics			Bactrim DS	Sulfameth oxazole/ Trimethop rim DS

# **Brand Name Code**

This is a 1-character field.

The Brand Name Code indicates the type of name used in the Drug Name [Data Element Code F007]. The Brand Name Code is a general Name Type Code for all products sharing a GPI. The value is determined by the Name Type Code [Data Element Code H073] values for the NDCs associated to the DDID.

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#### Valid Values:

Value	Description
T	Trademarked Name
В	Branded Generic Name
G	Generic Name

### Example:

Trademarked Name (T)	Branded Generic Name (B)	Generically Named (G)
Esgic Oral Capsule 50-325-	Margesic Oral Capsule	Butalbital-APAP-Caffeine
40 MG	50-325-40 MG	Oral Capsule 50-325-40 MG
Tylenol Oral Tablet 325 MG	Non-Aspirin Pain Relief Oral Tablet 325 MG	Acetaminophen Oral Tablet 325 MG
Chlor-Trimeton Oral Tablet	Aller-Chlor Oral Tablet	Chlorpheniramine Maleate
4 MG	4 MG	Oral Tablet 4 MG

Note	

In this context, the definition of a Branded Generic Name is a name accepted as an industry standard for a specific formulation used by more than one manufacturer/distributor. This name is also used by non-research and development (generic) manufacturers to represent their version of a generic product.

# **Name Source Code**

This is a 1-character field.

The Name Source Code indicates if at least one NDC is marketed with this drug description or if a generic drug description has been created.

#### Valid Values:

Value	Description
Р	Product does exist in NDC File
G	Product does not exist in NDC File
S	Name from Synonym

|--|

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#### Example:

Drug Name	Dosage Form	Name Source Code	Multi- Source Code	Brand Name Code
Afinitor	Tabs	Р	N	Т
Everolimus	Tabs	G	N	G
Amoxicillin	Caps	Р	Υ	G
Mexiletine HCI	Caps	Р	N	G

When generic-named drugs are initially introduced to the market, this value will change from a "G" to a "P". When generic-named drugs are removed from the market, this value will change from a "P" to a "G". To list all generic drug products, the search must find all "G" and "P" Name Source Codes.

Note	The Name Source Code does <b>not</b> indicate the type of name. Refer to the
	Brand Name Code for this information. Generic drug product records can
	have a "G" or "P" Name Source Code.

## **Generic Product Identifier**

This is a 14-character field.

The Generic Product Identifier (GPI) categorizes drug products by a hierarchical therapeutic classification scheme. The GPI defines pharmaceutically equivalent drug products that are identical in:

- active ingredient(s)
- dosage form
- route
- strength or concentration

The DDID for a brand name (for example, Lipitor Oral Tablet 10 MG), and the DDID for its corresponding generic name (for example, Atorvastatin Calcium Oral Tablet 10 MG) will be associated with the same GPI.

For more information, go to Chapter 2, "Editorial Policies".

# **Knowledge Base Drug Code**

This is a 10-digit numeric field.

The Knowledge Base Drug Code (KDC) is a proprietary Wolters Kluwer Clinical Drug Information concept that defines a drug in terms of its ingredients. Single ingredient drugs (for example, acetaminophen) are assigned a KDC. Multiple

4-24 MED-File v2 Published: 11/11 Revised: 04/18 ingredient drugs (for example, acetaminophen + hydrocodone) are assigned a KDC that represents the ingredient combination.

Note	The KDC is not a hierarchical value and does not correlate to the GPI in any
	way.

For more information, go to Retrieving KDCs for a Dispensable Drug in Chapter 5: Applications.

# **New Drug Descriptor Identifier**

This is a 6-digit numeric field.

The New Drug Descriptor Identifier allows tracking of changes to the DDID.

Note	This field is only present for records with a Transaction CD of D. "D" is in an Incremental Update and is not present in a Total Database.
Note	DDIDs that are removed from the Drug Name File will continue to appear in the Dispensable Drug File.

# Screenable Flag

This is a 1-character field.

The Screenable Flag is used to determine whether the drug name alone has a unique KDC and GPI.

#### Valid Values:

Value	Description
Υ	Screenable by name alone
N	Product has multiple GPIs and/or KDCs

The below conditions occur when one or both of the following exists when Screenable Flag is "N":

- The Generic Product Identifier [Data Element F075] is blank.
- The KDC Flag [Data Element Code F106] is "U".

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# **KDC Flag**

This is a 1-character field.

The KDC Flag indicates KDC association to a drug product.

### Valid Values:

Value	Description
Υ	Drug product has a KDC
N	Drug product does not have a KDC
U	Undetermined (under review)

# **Local/Systemic Code**

This is a 1-character field.

The Local/Systemic Code indicates if the drug product has a local or systemic effect. The value is generalized to represent all products sharing a DDID.

#### Valid Values:

Code	Description
0	Undetermined
1	Local
2	Oral
3	Parenteral
4	Systemic
5	Does Not Apply

# **Maintenance Drug Code**

This is a 1-character field.

The Maintenance Drug Code indicates whether or not the drug is considered a maintenance drug.

#### Valid Values:

Value	Description
0	Undetermined
1	Not a Maintenance Drug
2	Maintenance Drug

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# Form Type Code

This is a 1-character field.

The Form Type Code indicates the form of the medication when administered to a patient. The form may be different at this stage than it is when packaged and sold by the manufacturer. The value is generalized to represent all products sharing a DDID.

The Valid Values and Examples are:

Value	Description	Example
0	Undetermined	
1	Gas	NITROUS OXIDE (GAS)
2	Liquid	K-LYTE (EFFERVESCENT TABLETS)
3	Other	FLEET PREP KIT #2 (Bowel Prep kit)
4	Solid	VICODIN (TABLETS)

### Internal - External Code

This is a 1-character field.

The Internal-External Code complements the Route of Administration Code. The value is generalized to represent all products sharing a DDID.

The Valid Values and Examples are:

Value	Description	Example
0	Undetermined	
1	Combination of Internal and External	Dulcolax Bowel Prep Kit
2	Externally administered	Diprolene Ointment
3	Internally administered	Crestor 10 MG Tablet
4	Different than above	Clinitest Tablets

# **Single - Combination Code**

This is a 1-character field.

The Single-Combination Code distinguishes between products containing a single, active ingredient and a combination of two or more active ingredients. The value is generalized to represent all products sharing a DDID.

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The Valid Values and Examples are:

Value	Description	Example
0	Undetermined	Align (*Probiotic Product - Cap**)
1	Combination	Vytorin (Ezetimibe-Simvastatin)
2	Single	Zetia (Ezetimibe)

# **Representative GPI Flag**

This is a 1-character field.

The Representative GPI Flag indicates whether there is an exact match to a GPI or if multiple GPIs exist and a Representative GPI has been assigned.

#### Valid Values:

Value	Description
0	Unassigned
1	Exact Match GPI
2	Representative GPI

# Representative KDC Flag

This is a 1-character field.

The Representative KDC Flag indicates whether there is an exact match to a KDC or if multiple KDCs exist and a Representative KDC has been assigned.

#### Valid Values:

Value	Description
0	Unassigned
1	Exact Match KDC
2	Representative KDC

### Reserve

This is a 6-character field.

The Reserve field is an unused field that may be used at a future date.

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## **Transaction CD**

This is a 1-character field.

The Transaction CD indicates the file activity that last occurred for a record.

The current values are:

Value	Description
Α	Add
С	Change
D	Delete
b⁄	No Change

Note All Transaction CDs are blank for Total Databases.	
---	--

# **Last Change Date**

This is an 8-digit numeric field.

The Last Change Date identifies the most recent build date any field in the record was changed.

This date is in Gregorian format.

# **TC-GPI Name File**

### (MF2TCGPI)

The TC-GPI Name File provides Wolters Kluwer Clinical Drug Information's Therapeutic Classification System (TCS) hierarchy and names for each level of the hierarchy, including the GPI.

It may be appropriate in your application to separate Record Type Code 5 (GPI records) from the other Record Type Codes that represent the hierarchical system classification. This may provide efficiencies in storage or processing. Either way, to gain maximum benefit, all records and all fields, with the possible exception of the Transaction CD, should be stored in their entirety.

The TC-GPI Name File contains the following data elements:

Code	Data Element Name	Record Position	Type/Length	Picture
G001	TC-GPI Key	1-14	C/14	X(14)
G015	Record Type Code	15-15	C/1	Х
G016	TC-GPI Name	16-75	C/60	X(60)
G076	TC Level Code	76-77	C/2	X(2)
G078	Reserve	78-87	C/10	X(10)
G088	Transaction CD	88-88	C/1	Х
G089	Last Change Date	89-96	N/8	9(8)

**Note** The shaded rows represent the unique key into the file.

# **TC-GPI Key**

This is a 14-character field.

The TC-GPI Key allows access to Wolters Kluwer Clinical Drug Information's TCS. Record Types 0, 1, 2, 3, 6, and 4 are represented by a code of increasing specificity that is left-justified. Record Types of 7 are 12 characters long. Record Types of 5 are 14 characters long and are referred to as the Generic Product Identifier (GPI).

The GPI denotes pharmaceutically equivalent drug products. Products having the same 14-character GPI are identical with respect to active ingredient(s), dosage form, route, and strength or concentration. The GPI does not consider the presence of inactive ingredients. Each unique GPI corresponds to a descriptive GPI Generic Name (for example, 65991002050315, Acetaminophen w/ Codeine Tab 300-30 MG).

For more information, go to Chapter 2, "Editorial Policies".

# **Record Type Code**

This is a 1-character field.

The Record Type Code indicates the level of the TC-GPI Name [Data Element Code G016]. When these Therapeutic Classification records are used in addition to the GPI Generic Name, the hierarchy within Wolters Kluwer Clinical Drug Information's TCS is more apparent to the end-user.

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#### Valid Values:

Value	Description	TC Level Code	TC-GPI Key
0	Therapeutic Class Range	00	00
1	Drug Group	02	12
2	Drug Class	04	12-34
3	Drug Subclass	06	12-34-56
6	Drug Base Name	08	12-34-56-78
4	Drug Name/Drug Name Extension	10	12-34-56-78-90
7	Drug Name and Dosage Form	12	12-34-56-78-90-12
5	Full GPI with Drug Strength and Str UM	14	12-34-56-78-90-12-34

## **TC-GPI Name**

This is a 60-character field.

The Therapeutic Classification-Generic Product Identifier (TC-GPI) file contains the textual descriptions for the various levels of the classification system.

Depending on implementation, it may be desirable to separate Record Type 5 from the other Record Types (to remove the hierarchical system classification records from the GPI records) to gain efficiencies in storage or processing.

### TC Level Code

This is a 2-character field.

The TC Level Code defines the level of the therapeutic classification hierarchy based on the number of significant characters that are defined.

#### Valid Values:

Value	Description
00	Therapeutic Class Range
02	Drug Group
04	Drug Class
06	Drug Subclass

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Value	Description
08	Drug Base Name
10	Drug Name/Drug Name Extension
12	Drug Name and Dosage Form
14	Full GPI with Drug Strength and Str UM

## Reserve

This is a 10-character field.

The Reserve field is an unused field that may be used at a future date.

## **Transaction CD**

This is a 1-character field.

The Transaction CD indicates the file activity that last occurred for a record.

#### Valid Values:

Value	Description
Α	Add
С	Change
D	Delete
b⁄	No Change

|--|

# **Last Change Date**

This is an 8-digit numeric field.

The Last Change Date identifies the most recent build date any field in the record was changed.

This date is in Gregorian format.

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# **NDC** File

## (MF2NDC)

The NDC File contains specific information regarding distinct products in the marketplace which are identified by a National Drug Code (NDC). Drug products not identified by an NDC, are identified by Universal Product Codes (UPCs) or Health-Related Items (HRIs).

While the Drug Name File (MF2NAME) groups information and assigns certain attributes for multiple NDC-UPC-HRIs that share a single DDID, the NDC File assigns many of these attributes specific to the unique NDC-UPC-HRI. Use of the NDC File is warranted when the following occurs:

- Specificity at the NDC-UPC-HRI level is needed for certain attributes such as the following:
  - > TFF Code
  - > DEA Class Code
  - > DESI Code
  - > RX-OTC Indicator Code
  - > Multi-Source Code
  - > Name Type Code
- Additional attributes not found in the Drug Name File are needed such as the following:
  - > Innerpack Code
  - > Storage Condition Code
  - > Limited Distribution Code
- Use of drug pricing is planned in your application
- Information on market availability of drug products (inactive/active status) tied to a system involving reimbursement or claims is needed for submission
- When precise documentation of an NDC is essential, and there is no GPI or KDC information in the Drug Name File, and clinical screening is required

The NDC File contains the following data elements:

Code	Data Element Name	Record Position	Type/Length	Picture
H001	NDC-UPC-HRI	1-11	C/11	X(11)
H012	Drug Descriptor Identifier	12-17	N/6	9(6)
H018	TEE Code	18-19	C/2	X(2)
H020	DEA Class Code	20-20	C/1	Х
H021	DESI Code	21-21	C/1	Х
H022	RX-OTC Indicator Code	22-22	C/1	Х

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Code	Data Element Name	Record Position	Type/Length	Picture
H023	Generic Product Packaging Code	23-30	C/8	X(8)
H031	Old NDC-UPC-HRI	31-41	C/11	X(11)
H042	New NDC-UPC-HRI	42-52	C/11	X(11)
H053	Repackage Code	53-53	C/1	X
H054	ID Number Format Code	54-54	C/1	Х
H055	Third-Party Restriction Code	55-55	C/1	Х
H056	Knowledge Base Drug Code	56-65	N/10	9(10)
H066	KDC Flag	66-66	C/1	Х
H067	Medi-Span Labeler Identifier	67-71	N/5	9(5)
H072	Multi-Source Code	72-72	C/1	Х
H073	Name Type Code	73-73	C/1	Х
H074	Item Status Flag	74-74	C/1	Х
H075	Innerpack Code	75-75	C/1	Х
H076	Clinic Pack Code	76-76	C/1	Х
H077	Reserve-1	77-78	C/2	X(2)
H079	PPG Indicator Code	79-79	C/1	Х
H080	HFPG Indicator Code	80-80	C/1	Х
H081	Dispensing Unit Code	81-81	C/1	Х
H082	Dollar Rank Code	82-82	C/1	Х
H083	Rx Rank Code	83-83	C/1	Х
H084	Storage Condition Code	84-84	C/1	Х
H085	Limited Distribution Code	85-86	C/2	X(2)
H087	Old Effective Date	87-94	N/8	YYYYMMDD
H095	New Effective Date	95-102	N/8	YYYYMMDD
H103	Next-Smaller NDC Suffix Number	103-104	C/2	X(2)
H105	Next-Larger NDC Suffix Number	105-106	C/2	X(2)
H107	Reserve-2	107-119	C/13	X(13)
H120	Transaction CD	120-120	C/1	Х
H121	Last Change Date	121-128	N/8	9(8)

**Note** The shaded row represents the unique key into the file.

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## NDC-UPC-HRI

This is an 11-character field.

NDCs, UPCs, and HRIs are 10-character codes used to identify drug products. Surgical supplies and non-prescription drug products may have an NDC and an HRI or UPC according to the standards set forth by the Uniform Product Code Council, Inc. These codes are converted to eleven characters according to NCPDP standards.

For more information regarding the NDC-UPC-HRI, go to Chapter 2, "NDC-UPC-HRI".

For more information regarding formatting of the NDC-UPC-HRI, see ID Number Format Code.

# **Drug Descriptor Identifier**

This is a 6-digit numeric field.

The Drug Descriptor Identifier (DDID) is six digits identifying a unique combination of Drug Name, Route, Dosage Form, Strength, and Strength Unit of Measure. The value of the identifier itself has no meaning. It is used to identify a unique product with respect to these fields alone. It does not distinguish products by Package Size, TEE Code, DESI Code, DEA Class Code, Brand Name Code, or various other attributes.

#### Example:

Drug Descriptor ID	Drug Name	Route	Dosage Form	Strength	SUM
001847	Artificial Tears	OP	OINT		
023426	VinCRIStine Sulfate	IV	SOLN	1	MG/ML
032186	Diltiazem HCI CR	PO	CP12	120	MG
088732	Vytorin	PO	TABS	10-10	MG
089216	HalfLytely Bowel Prep	PO	KIT	5-210	MG-GM

#### TEE Code

This is a 2-character field.

The Therapeutic Equivalence Evaluation (TEE) Code is a two-character code indicating the FDA rating of the therapeutic equivalence of a drug product with other pharmaceutically equivalent drug products, as published in the *Orange Book*. This code is used in conjunction with the Generic Product Identifier [Data Element Code F075]. The GPI groups pharmaceutically equivalent drug products, and, in that context, the TEE Code is meaningful.

Note

TEE Codes beginning with "A" (except values of "A1", "A2", "A3" and "A4") indicate drug products that are therapeutically equivalent to other pharmaceutically equivalent products. Products with an "A" TEE Code are generally considered interchangeable with pharmaceutically equivalent drug products, subject to individual state regulations governing product substitution. In the exception noted above, the full two-character TEE Code is necessary to find therapeutically equivalent drugs (such as when comparing a GPI category containing both "A1", "A2", "A3" and "A4" ratings).

#### Valid Values:

Code	Description	Definition
AA	No Bioequivalence Problems	Products having no bioequivalence problems in conventional dosage forms
AB	Bioequivalence Resolved	Products meeting necessary bioequivalence requirements
AN	Soln/Powd Aerosol - OK	Solutions and powders for aerosolization
AO	Injectable Oil Solutions - OK	Injectable oil solutions (same concentration and vehicle)
AP	Injectable H2O Solutions - OK	Injectable aqueous solutions
AT	Topical products - OK	Topical products
A1	Bioequivalence Resolved	Equivalent to <i>Orange Book</i> value of "AB1".  Products with this code are only equivalent to other products with the same GPI and the same TEE Code.
A2	Bioequivalence Resolved	Equivalent to <i>Orange Book</i> value of "AB2".  Products with this code are only equivalent to other products with the same GPI and the same TEE Code.
A3	Bioequivalence Resolved	Equivalent to <i>Orange Book</i> value of "AB3".  Products with this code are only equivalent to other products with the same GPI and the same TEE Code.
A4	Bioequivalence Resolved	Equivalent to <i>Orange Book</i> value of "AB4".  Products with this code are only equivalent to other products with the same GPI and the same TEE Code.

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Code	Description	Definition
BC	CRTB/CRCP/CR - INJS Problems	Controlled-release dosage forms
BD	Al or DF Documented Problems	Ingredients and dosage forms with documented bioequivalence problems
BE	ECTB Oral Problems	Enteric-coated oral dosage forms
BN	Aerosol - Nebulizer Problems	Products in aerosol-nebulizer drug delivery systems
BP	Al or DF Potential Problems	Active ingredients and dosage forms with potential bioequivalence problems (for example, injectable suspensions)
BR	Supp/Enem Systemic Problems	Suppositories or enemas for systemic use
BS	Drug Standard Problems	Products having drug standard deficiencies
BT	Topical Problems	Topical products with bioequivalence issues
ВХ	Insufficient Data	Drug products for which data are insufficient to determine therapeutic equivalence
B*	Requires Further	Products requiring further FDA investigation to
	Investigation	determine therapeutic equivalence
NA	Not Available	Information is not available
NR	Not Rated	Drug product has not yet been rated

# **DEA Class Code**

This is a 1-character field.

The DEA Class Code identifies federally controlled substances classified by the Drug Enforcement Administration (DEA).

## Valid Values:

Value	Description	Definition	Abbreviation
1	No accepted medical use	Schedule I: High abuse potential; medical use not accepted (such as heroin, marijuana, and LSD)	C-I
2	High abuse, severe dependence liability	Schedule II: High abuse potential with severe dependence liability (such as narcotics, amphetamines, and barbiturates)	C-II

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Value	Description	Definition	Abbreviation
3	Moderate dependence liability	Schedule III: Less abuse potential than Schedule II drugs and moderate dependence liability (such as nonbarbiturate sedatives, nonamphetamine stimulants, anabolic steroids, and limited amounts of certain narcotics)	C-III
4	Limited abuse potential	Schedule IV: Less abuse potential than Schedule III drugs and limited dependence liability (such as some sedatives, anti-anxiety agents, and non-narcotic analgesics)	C-IV
5	Limited abuse potential, small amounts	Schedule V: Limited abuse potential; primarily small amounts of narcotics (codeine) used as antitussives or antidiarrheals; under federal law, limited quantities of certain C-V drugs may be purchased directly from a pharmacist without a prescription; can be either prescription or OTC	C-V
b'	DEA Class Code is not applicable	A DEA Class Code is not applicable	

For more information, go to Chapter 2, "DEA Class Code".

## **DESI Code**

This is a 1-character field.

The DESI Code identifies the stage of review for drugs pending final resolutions of efficacy by the FDA's Drug Efficacy Study Implementation (DESI) program.

"IRS" refers to drugs that are identical, related, or similar to current DESI drugs. "NOOH" refers to Notice of Opportunity for a Hearing, which is published in the *Federal Register*.

4-38 MED-File v2 Published: 11/11 Revised: 04/18 According to the FDA, the following codes are valid. Additionally, Wolters Kluwer Clinical Drug Information includes the value of "b" (blank) for non-drug and other non-applicable drug products.

Value	Description	Definition
p,	Non-drug and other non-applicable items	Non-drug and other non-applicable items
2	Determined to be safe and effective	Non-DESI/IRS drugs or DESI/IRS drugs determined safe and effective
3	Under review (NOOH has not been issued)	DESI/IRS drugs under review (NOOH has not been issued)
4	Less than effective for some indications	LTE DESI/IRS drugs for some indications
5	Less than effective for all indications	LTE DESI/IRS drugs for all indications
6	Less than effective, withdrawn	LTE DESI/IRS drugs withdrawn from the market

For more information, go to Chapter 2, "DESI Code".

## **RX-OTC Indicator Code**

This is a 1-character field.

The RX-OTC Indicator Code indicates federal prescription (Rx) or Over-the-Counter (OTC) status. If coded "R" or "S", the drug product requires a prescription; if coded "O" or "P", the drug product is an OTC product and does not require a prescription. The "S" and "P" codes also indicate the drug product is available from more than one manufacturer.

#### Valid Values:

Value	Description
0	OTC (single source)
Р	OTC (multiple source)
R	Rx (single source)
S	Rx (multiple source)

The RX-OTC Indicator Code is coded in conjunction with the Multi-Source Code [Data Element Code H072] as follows:

Value	Description Using Multisource Codes
0	OTC product with a Multi-Source Code of "N"
Р	OTC product with a Multi-Source Code of "O", "M", or "Y"

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Value	Description Using Multisource Codes
R	Rx product with a Multi-Source Code of "N"
S	Rx product with a Multi-Source Code of "O", "M", or "Y"

# **Generic Product Packaging Code**

This is a 8-character field.

The Generic Product Packaging Code (GPPC) identifies unique combinations of the following fields:

Data Element Name	Data Element Code
Generic Product Identifier	J028
Package Description Code	J026
Package Size	J009
Package Size Unit of Measure	J018
Package Quantity	J020
Unit-Dose/Unit-of-Use Package Code	J025

For more information, go to Chapter 2, "Generic Product Packaging Code".

### Old NDC-UPC-HRI

This is an 11-character field.

When the NDC-UPC-HRI for a product changes, the following occurs:

- Two records are output at the time of the change
- The old NDC-UPC-HRI record will include an Item Status Flag of "I" to indicate the NDC-UPC-HRI is now inactive
- A new NDC-UPC-HRI record will be output with a Transaction CD of "A" to indicate the record is a new addition to the file
- The old NDC-UPC-HRI value will be included in the Old NDC-UPC-HRI field of the new record

### **New NDC-UPC-HRI**

This is an 11-character field.

When the NDC-UPC-HRI for a product changes, the following occurs:

- Two records are output at the time of the change
- The new NDC-UPC-HRI record will be output with a Transaction CD of "A" to indicate the record is a new addition to the file

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- The old NDC-UPC-HRI record will include an Item Status Flag of "I" to indicate the NDC-UPC-HRI is now inactive
- The new NDC-UPC-HRI value will be included in the Old NDC-UPC-HRI field of the new record

# Repackage Code

This is a 1-character field.

The Repackage Code identifies products that have been repackaged for use by:

- mail order suppliers
- · home health care agencies
- nursing homes
- physicians
- others

Repackaged products include both brand name and generic drug products.

#### Valid Values:

Code	Description
Х	Repackaged Product
b⁄	Not Repackaged

### **ID Number Format Code**

This is a 1-character field.

The ID Number Format Code identifies the format of the NDC-UPC-HRI [Data Element Code H001, H031, and H042]. Use the ID Number Format Code with an NDC, UPC, or HRI to determine

- where to place dashes when formatting for display
- how to convert from the 10- to 11-digit format
- how to convert from the 11- to 10-digit format

## Valid Values:

Value	Represents	ID Type
1	4-4-2	NDC
2	5-3-2	NDC
3	5-4-1	NDC
4	4-6	HRI

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Value	Represents	ID Type
5	5-5	UPC or HRI
6	5-4-2	NDC

The codes convert as follows:

NDC		NCPDP Standard 11- character NDC	11-character NDC (with hyphens)	ID Format Code
4-4-2 (9999-9999-99)		5-4-2 (09999999999)	09999-9999-99	1
5-3-2 (99999-999-99)		5-4-2 (99999099999)	99999-0999-99	2
5-4-1 (99999-9999-9)	Converts	5-4-2 (99999999999)	99999-9999-09	3
5-4-2 (99999-9999-99	То	5-4-2 (99999999999)	99999-9999-99	6
4-6 (9999-999999)		5-6 (09999999999)	9999-999999	4
5-5 (99999-99999)		5-6 (99999099999)	99999-99999	5

# **Third-Party Restriction Code**

This is a 1-character field.

The Third-Party Restriction Code can be used by Third Party Administrators (TPAs) for identifying drug products for formulary exclusion (such as oral contraceptives) or inclusion (for example, vitamins).

# **Knowledge Base Drug Code**

This is a 10-digit numeric field.

The Knowledge Base Drug Code (KDC) is a concept used by Wolters Kluwer Clinical Drug Information that defines a drug in terms of its ingredients. Single ingredient drugs (for example, acetaminophen) are assigned a KDC. Multiple ingredient drugs (for example, acetaminophen + hydrocodone) are assigned a KDC that represents the ingredient combination.

When a KDC Flag [Data Element Code H066] is "N" or "U", the KDC will be zero-filled in this field.

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Note	The KDC is not a hierarchical value and does not correlate to the GPI in any
	way.

For more information, go to Chapter 2, "Knowledge Base Drug Code".

# **KDC Flag**

This is a 1-character field.

The KDC Flag indicates KDC association to a drug product.

#### Valid Values:

Value	Description
Υ	Drug product has a KDC
N	Drug product does not have a KDC
U	Undetermined (under review)

# Medi-Span Labeler Identifier

This is a 5-digit numeric field.

The Medi-Span Labeler Identifier links the drug product to its manufacturer or distributor. Most Medi-Span Labeler Identifiers are derived from the labeler code segment of the NDC-UPC-HRI. However, in some cases, the Medi-Span Labeler Identifier differs from the labeler code segment of the NDC-UPC-HRI, so that the accurate division name within the manufacturer or distributor can be associated with the drug product.

For more information, go to Chapter 2, "Medi-Span Labeler Identifier".

## **Multi-Source Code**

This is a 1-character field.

The Multi-Source Code identifies drug products as either single- or multiple-source original drug products or a generic copy of the standard drug product. This code is provided by Wolters Kluwer Clinical Drug Information as a general guideline. Drug product price may be needed as a determining factor for generic substitution.

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## Valid Values:

Value	Description	Definition
N	Single-source product	Single-source product available from one labeler.
M	Single-source, co-licensed product	Product is co-licensed and considered a single-source product despite being available from multiple labelers.
0	Multi-source, originator product	Product available from multiple labelers considered to be the industry standard.
Υ	Multi-source product	Multi-source product available from multiple labelers.

**Note** Products are designated "N" when the Multi-Source Code does not apply. For example, medical devices, partial GPIs, biologicals, and prenatal vitamins.

## Example:

Condition	N	M	0	Υ
Single-Source	Lantus	-	-	-
	lnj			
Co-licensed	-	Adderal XR Oral	-	-
		Capsule Extended		
		Release 24 Hour 10		
		MG		
		AND		
		Amphetamine-		
		Dextroamphetamine		
		Oral Capsule		
		Extended Release 24		
		Hour 10 MG		
Original with	-	-	Valium 5	Diazepam 5
Generics			mg	mg
Former Co-	-	-	Septra DS	SMZ/TMP DS
licensing with			Bactrim DS	Sulfamethox-
Generics				azole/
				Trimethoprim
				DS

**Note** These codes are subject to change as more information is made available to Wolters Kluwer Clinical Drug Information.

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# **Name Type Code**

This is a 1-character field.

The Name Type Code indicates the type of name used in the Drug Name [Data Element Code F007].

#### Valid Values:

Value	Description
G	Generic Name
Т	Trademarked Name
В	Branded Generic Name

## Example:

Trademarked Name (T)	Branded Generic Name (B)	Generically Named (G)
Esgic Oral Capsule 50-325-	Margesic Oral Capsule	Butalbital-APAP-Caffeine
40 MG	50-325-40 MG	Oral Capsule 50-325-40 MG
Tylenol Oral Tablet 325 MG	Non-aspirin Pain Relief Oral Tablet 325 MG	Acetaminophen Oral Tablet 325 MG
Chlor-Trimeton Oral Tablet	Aller-Chlor Oral Tablet	Chlorpheniramine Maleate
4 MG	4 MG	Oral Tablet 4 MG

# **Item Status Flag**

This is a 1-character field.

The Item Status Flag distinguishes between active and inactive NDCs and allows the Transaction CD to clearly reflect the add, change, and delete status of the record.

Additionally, drug products inactive for greater than 48 months do not appear in the Total Database and are output in the Incremental Updates (one time only) with a "D" Transaction CD and a "Z" Item Status Flag. These records can be stored in your historical files.

#### Valid Values:

Value	Description
Α	Active
1	Inactive

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Value	Description
0	Override
Z	Inactive Greater than 48 Months

# **Innerpack Code**

This is a 1-character field.

The Innerpack Code identifies the NDC that appears on items contained within a large carton. These innerpack NDCs differ slightly from the carton NDC and may not be sold separately by the manufacturer. However, they may be sold individually by the wholesaler. Their prices are calculated from the carton NDC and are updated when a price change occurs to the carton NDC.

#### Valid Values:

Value	Description	Definition
Υ	Yes	Item is an innerpack and is not sold separately.
N	No	Item is not an innerpack.

## **Clinic Pack Code**

This is a 1-character field.

The Clinic Pack Code identifies drug products distributed to patients as samples (such as "clinic packs" and "institutional packs") by hospitals, clinics, manufacturers, and physicians.

Clinic packs generally have no price associated with them.

#### Valid Values:

Value	Description	Definition
Υ	Yes	Item is a clinic pack.
N	No	Item is not a clinic pack.

## Reserve-1

This is a 2-character field.

The Reserve-1 field is an unused field that may be used at a future date.

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## **PPG Indicator Code**

This is a 1-character field.

The PPG Indicator Code identifies approximately 5,000 of the most commonly stocked prescription drug products in the retail pharmacy environment.

#### Valid Values:

Value	Description
Υ	Included in the PPG
p,	Not included in the PPG

### **HFPG Indicator Code**

This is a 1-character field.

The HFPG Indicator Code contains all drug products identified with a PPG Indicator Code of "Y", in addition to unit-dose and injectables needed by hospitals and extended-care facilities - approximately 10,000 drug products.

#### Valid Values:

Value	Description
Υ	Included in the HFPG
b'	Not included in the HFPG

# **Dispensing Unit Code**

This is a 1-character field.

The Dispensing Unit Code indicates whether the NDC-UPC-HRI represents the usual dispensing sizes for tablets, capsules, and liquids.

#### Valid Values:

Value	Description
U	Usual Dispensing Size
p,	Other Than Usual Dispensing Size

Wolters Kluwer Clinical Drug Information uses the following packages for dispensing sizes for tablets, capsules, and liquids only:

Dosage Form	Package Size	Dispensing Unit Code
Tablets and Capsules	100	U
Liquids	480 ml (pint)	U

Note	Normal dispensing size for liquids is 480 ml. Pints that only contain 473 ml
	are not coded with a Dispensing Unit Code of $U$ .

## **Dollar Rank Code**

This is a 1-character field.

The Dollar Rank Code indicates the drug product's annual industry dollar sales rank according to independent research audits.

### Valid Values:

Value	Description
0	Not Ranked
1	Ranked between 1 and 100
2	Ranked between 101 and 200
3	Ranked between 201 and 300
4	Ranked between 301 and 400
5	Ranked between 401 and 500

A Dollar Rank Code exists for the Top 500 drug products at the NDC-UPC-HRI level. Therefore, it is possible for similar products with different strengths or package sizes to have different Dollar Rank Codes.

### Rx Rank Code

This is a 1-character field.

The Rx Rank Code indicates the prescription-velocity rank according to independent research audits. These audits review annual industry prescription volumes.

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#### Valid Values:

Value	Description
0	Not Ranked
1	Ranked between 1 and 100
2	Ranked between 101 and 200
3	Ranked between 201 and 300
4	Ranked between 301 and 400
5	Ranked between 401 and 500

An Rx Rank Code exists for the Top 500 drug products at the NDC-UPC-HRI level. Therefore, it is possible for similar products with different strengths or package sizes to have different Rx Rank codes.

# **Storage Condition Code**

This is a 1-character field.

The Storage Condition Code indicates the conditions under which a drug must be stored, prior to dispensing, according to the *United States Pharmacopoeia National Formulary* (USP-NF) specifications.

#### Valid Values:

Value	Description
N	Normal (room temperature)
R	Refrigerated
F	Frozen
b'	Not Available

Note	Drug products subject to reconstitution, such as Amoxicillin and Clavulanate
	Potassium Powder for Suspension, are coded with the Storage Condition
	Code N, which represents normal preconstitution storage condition. The
	end-user would inform the patient of the refrigeration requirements after
	reconstitution.

# **Limited Distribution Code**

The Limited Distribution Code is used to denote if there are restricted distributions for a product. For example, this code denotes a private labeler, availability restricted to one region, and so on.

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#### Valid Values:

Value	Definition
00	NOT APPLICABLE
01	PRIVATE LABELER
02	AVAILABLE IN PUERTO RICO ONLY
03	COMPOUNDING LABELER

|--|

### Old Effective Date

This is an 8-digit numeric field.

The Old Effective Date is associated to the Old NDC-UPC-HRI and represents its inactive date. The date is populated in the new NDC-UPC-HRI when the Old NDC-UPC-HRI is populated.

The date is in Julian format.

## **New Effective Date**

This is an 8-digit numeric field.

The New Effective Date is associated to the New NDC-UPC-HRI and represents the effective date for the new NDC-UPC-HRI. The date is populated in the old NDC-UPC-HRI record when the New NDC-UPC-HRI field is populated.

In some instances, the New NDC-UPC-HRI is replacing an old NDC-UPC-HRI that is replacing an even older NDC-UPC-HRI, all within the same MED-File v2 update. The New Effective Date is associated to the New NDC-UPC-HRI and represents the effective date for the new NDC-UPC-HRI. The date is populated in the old NDC-UPC-HRI record when the New NDC-UPC-HRI field is populated. In addition, the New Effective Date field is populated in the older NDC-UPC-HRI record to reflect the effective date for the old NDC-UPC-HRI, even though the old NDC-UPC-HRI was replaced with the New NDC-UPC-HRI.

The date is in Julian format.

4-50 MED-File v2 Published: 11/11 Revised: 04/18 Note This field is blank when no data is present.

## **Next-Smaller NDC Suffix Number**

This is a 2-character field.

When available, the Next-Smaller NDC Suffix Number identifies the last one or two-digit suffix for the next smaller size of a drug product. This field is used for products identified by an NDC. UPCs, HRIs, innerpacks, clinic packs, and unit-dose items are not considered.

## Example

Drug Name	NDC	Next-Smaller NDC Suffix Number
Nexium 20 mg 90s	00186-5020-54	31
Nexium 20 mg 30s	00186-5020- <u>31</u>	

# **Next-Larger NDC Suffix Number**

This is a 2-character field.

When available, the Next-Larger NDC Suffix Number identifies the last one or two-digit suffix for the next larger size of a drug product. This field is used for products identified by an NDC. UPCs, HRIs, clinic packs, innerpacks, and unit-dose items are not considered.

#### Example

Drug Name	NDC	Next-Larger NDC Suffix Number
Nexium 20 mg 90s	00186-5020- <u>54</u>	
Nexium 20 mg 30s	00186-5020-31	54

## Reserve-2

This is a 13-character field.

The Reserve-2 field is an unused field that may be used at a future date.

### **Transaction CD**

This is a 1-character field.

The Transaction CD indicates the file activity that last occurred for a record.

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#### Valid Values:

Value	Description
A	Add
С	Change
D	Delete
p,	No Change

### **Last Change Date**

This is an 8-digit numeric field.

The Last Change Date identifies the most recent build date any field in the record was changed.

This date is in Gregorian format.

#### **Transaction CD**

This is a 1-character field.

The Transaction CD indicates the file activity that last occurred for a record.

#### Valid Values:

Value	Description
Α	Add
С	Change
D	Delete
p,	No Change

|--|--|--|

## **Labeler File**

#### (MF2LAB)

The Labeler File provides a textual description for the Medi-Span Labeler Identifier.

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The Labeler	File contains	the following	data elements:

Code	Data Element Name	Record Position	Type/Length	Picture
1001	Medi-Span Labeler Identifier	1-5	N/5	9(5)
1006	Manufacturer's (Labeler) Name	6-35	C/30	X(30)
1036	Manufacturer's Abbreviated Name	36-45	C/10	X(10)
1046	Labeler Type Code	46-46	C/1	Х
1047	Reserve	47-55	C/9	X(9)
1056	Transaction CD	56-56	C/1	Х
1057	Last Change Date	57-64	N/8	9(8)

### Medi-Span Labeler Identifier

This is a 5-digit numeric field.

The Medi-Span Labeler Identifier links the drug product to its manufacturer or distributor. Most Medi-Span Labeler Identifiers are derived from the labeler code segment of the NDC-UPC-HRI. However, in some cases, the Medi-Span Labeler Identifier differs from the labeler code segment of the NDC-UPC-HRI, so that the accurate division name within the manufacturer or distributor can be associated with the drug product.

#### Example:

Medi-Span Labeler Identifier	Manufacturer's (Labeler) Name	Manufacturer's Abbreviated Name	Labeler Type Code
00067	NOVARTIS	NOV CON HE	В
00078	NOVARTIS	NOVARTIS	В
00904	MAJOR PHARMACEUTICALS	MAJOR	G
17191	BAX CORPORATION	BAXA CORP	0
55513	AMGEN	AMGEN	В

For more information, go to Chapter 2, "Medi-Span Labeler Identifier".

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### Manufacturer's (Labeler) Name

This is a 30-character field.

The Manufacturer's (Labeler) Name indicates the manufacturer, distributor, and/or division whose name is included on the label.

#### Example:

Medi-Span Labeler Identifier	Manufacturer's (Labeler) Name	Manufacturer's Abbreviated Name	Labeler Type Code
00067	NOVARTIS	NOV CON HE	В
00078	NOVARTIS	NOVARTIS	В
00904	MAJOR PHARMACEUTICALS	MAJOR	G
17191	BAX CORPORATION	BAXA CORP	0
55513	AMGEN	AMGEN	В

#### **Manufacturer's Abbreviated Name**

This is a 10-character field.

The Manufacturer's Abbreviated Name indicates the shortened name for the manufacturer, distributor, and/or division whose name is included on the label.

#### Example:

Medi-Span	Manufacturer's	Manufacturer's	Labeler
Labeler	(Labeler) Name	Abbreviated Name	Type Code
Identifier			
00067	NOVARTIS	NOV CON HE	В
00078	NOVARTIS	NOVARTIS	В
00904	MAJOR	MAJOR	G
	PHARMACEUTICALS		
17191	BAX CORPORATION	BAXA CORP	0
55513	AMGEN	AMGEN	В

## **Labeler Type Code**

This is a 1-character field.

4-54 MED-File v2 Published: 11/11 Revised: 04/18 The Labeler Type Code helps differentiate among manufacturers that produce

- innovator products
- generic products
- innovator and generic products

#### Valid Values:

Value	Description	Definition
В	Promoted as "Brand"	Labeler's products are priced or promoted as "Brand," "Originator," or "Innovator" products
G	Promoted as "Generic"	Labeler's products are priced or promoted as "Generic" products
0	Promoted as "Brand" or "Generic"	Labeler's products are priced or promoted as either "Brand" or "Generic" products

Note	The Labeler Type Code may change as labelers merge or as market
	strategies change.

#### Example:

Medi-Span Labeler Identifier	Manufacturer's (Labeler) Name	Manufacturer's Abbreviated Name	Labeler Type Code
00067	NOVARTIS	NOV CON HE	В
00078	NOVARTIS	NOVARTIS	В
00904	MAJOR PHARMACEUTICALS	MAJOR	G
17191	BAXA CORPORATION	BAXA CORP	0
55513	AMGEN	AMGEN	В

### Reserve

This is a 9-character field.

The Reserve field is an unused field that may be used at a future date.

### **Transaction CD**

This is a 1-character field.

The Transaction CD indicates the file activity that last occurred for a record.

#### Valid Values:

Value	Description
Α	Add
С	Change
D	Delete
b'	No Change

Note All Transaction CDs are blank for Total Database.	
--	--

## **Last Change Date**

This is an 8-digit numeric field.

The Last Change Date identifies the most recent build date any field in the record was changed.

This date is in Gregorian format.

## **GPPC File**

#### (MF2GPPC)

The Generic Product Packaging Code (GPPC) File defines the packaging fields represented by the Generic Product Packaging Code in the NDC File.

This file is related to the NDC File through the Generic Product Packaging Code in a one-to-many relationship. It is also related to the GPPC Price File through the Generic Product Packaging Code in a one-to-zero or one-to-many relationship.

Note	To view an exception to the data contained within the inactives file, go to
	Appendix F: Inactives File Exceptions.

The GPPC File contains the following data elements:

Code	Data Element Name	Record Position	Type/Length	Picture
J001	Generic Product Packaging Code	1-8	C/8	X(8)
J009	Package Size	9-17	N/9	9(6)V9(3)

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Code	Data Element Name	Record Position	Type/Length	Picture
J018	Package Size Unit of	18-19	C/2	X(2)
	Measure			
J020	Package Quantity	20-24	N/5	9(5)
J025	Unit-Dose/Unit-of-Use	25-25	C/1	Х
	Package Code			
J026	Package Description	26-27	C/2	X(2)
	Code			
J028	Generic Product	28-41	C/14	X(14)
	Identifier			
J042	Reserve	42-55	C/14	X(14)
J056	Transaction CD	56-56	C/1	Х
J057	Last Change Date	57-64	N/8	9(8)

Note The shaded row represents the unique key into the file.
--

## **Generic Product Packaging Code**

This is an 8-character field.

The Generic Product Packaging Code (GPPC) identifies unique combinations of the following fields:

Data Element Name	Data Element Code
Generic Product Identifier	J028
Package Description Code	J026
Package Size	J009
Package Size Unit of Measure	J018
Package Quantity	J020
Unit-Dose/Unit-of-Use Package Code	J025

The Generic Product Packaging Code (GPPC) defines a drug product and its packaging. The first five characters of the GPPC, referred to as the GPPC-Core, are random and represent the drug's GPI. The last three characters are referred to as the GPPC-Suffix and identify unique combinations of the fields in the table below.

Table 4-1: GPPC File Packaging Field Examples

GPPC	Package Size	Package Size Unit of Measure	Package Quantity	Unit-Dose/ Unit-of-Use Package	Package Description	Generic Product Identifier
09843001	100	Each	1	Unit-of-Use	Bottle	60204080100315 Zolpidem Tartrate Tab 10 MG
09843003	100	Each	1		Bottle	60204080100315 Zolpidem Tartrate Tab 10 MG
46788027	500	1			Bottle	60204080100410 Zolpidem Tartrate Tab CR 6.25 MG
46788028	100	Each	1	Unit-Dose	Box	60204080100410 Zolpidem Tartrate Tab CR 6.25 MG
03450583	15	Milliliter	100	Unit-Dose	Cup	642000100002010 Acetaminophen Soln 160 MG/5 ML

**Note** The Total Package Quantity can be calculated by multiplying the Package Size by the Package Quantity.

For more information, go to Chapter 2, "Generic Product Packaging Code".

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### **Package Size**

This is a 9-digit numeric field.

The Package Size represents the total size of the package in volume or number of units contained. In oral suspensions for reconstitution, the Package Size after reconstitution is the number shown in this field, as stated by the manufacturer.

For specific examples of this field, go to GPPC File Packaging Field Examples.

Note	Unit of use packets with a quantity of less than one, have a package size of 1.
Note	For injectables that can be reconstituted to a variable volume, the Package Size is "1".
Note	The Total Package Quantity can be calculated by multiplying the Package Size by the Package Quantity.

## **Package Size Unit of Measure**

This is a 2-character field.

The Package Size Unit of Measure identifies the unit of measure for the Package Size of the solid, liquid, or gas as dispensed. Wolters Kluwer Clinical Drug Information's assignment of this value is in accordance with the standards set forth by the National Council for Prescription Drug Programs (NCPDP).

#### Valid Values:

Value	Description
EA	Each
GM	Gram
ML	Milliliter

**Note** Unit of use packets with a quantity of less than one, have a package size unit of measure of EA.

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Note	For injectables that can be reconstituted to a variable volume, the Package
	Size Unit of Measure will be "EA".

For specific examples of this field, go to GPPC File Packaging Field Examples.

## **Package Quantity**

This is a 5-digit numeric field.

The Package Quantity identifies the number of individual containers or units per package as supplied by the manufacturer.

Note	The Total Package Quantity can be calculated by multiplying the Package
	Size by the Package Quantity.

For specific examples of this field, go to GPPC File Packaging Field Examples.

## Unit-Dose/Unit-of-Use Package Code

This is a 1-character field.

The Unit-Dose/Unit-of-Use Package Code identifies drug products which are packaged as "Unit-Dose" or "Unit-of-Use."

#### Valid Values:

Value	Description	Definition	
Х	Unit-Dose Packaging	Any drug product packaged and intended for	
		administration as a single dose at one time.	
		These drug products also maintain complete	
		labeling (UD cup, Strip Packaging tablet/	
		capsule, packet of 2 tablets/capsules that	
		constitute a single dose); this includes all	
		single-dose injections (such as PTV, SDV, amps,	
		syringes, and partial fills).	

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Value	Description	Definition
U	Unit-of-Use Packaging	Any packaged drug product in a standard quantity for a specific therapy suitable for direct dispensing to the patient. Examples include repackaged products, tubes of semisolids, potassium chloride powder packets, nicotine gum, and bulk over-the-counter products.
b'	Standard Packaging	Any drug product in which portions are removed for administration and dispensing. This portion does not have labeling for a single-dose unit.

For specific examples of this field, go to GPPC File Packaging Field Examples.

# **Package Description Code**

This is a 2-character field.

The Package Description Code indicates the container or package used for the drug product. The table below lists the current values.

Note	The two-character Package Description Code is not to be displayed or		
	provided in print form in end-user applications. The code should be		
translated to its corresponding Value Description as defined in the			
	Validation/Translation File. Significant patient safety issues are associated		
with the use of non-standard abbreviations such as those found			
	Package Description Code.		

Value	Description
AM	Ampule
AT	Atomizer
BG	Bag
BL	Blister
ВО	Bottle
ВХ	Box
CN	Can
CT	Cartridge
СР	Cup
CR	Crtrdg-NDL
DP	Disp Pack
DR	Drum
FC	Flex Cont
GC	Glass Cont
IH	Inhaler

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Value	Description
JR	Jar
PA	Pack
РВ	Pump BtI
PC	Plas Cont
PD	Punchcard
PG	Package
PK	Packet
PN	Pen
RL	Roll
SB	Spray Btl
SH	Sachet
SK	Stick
ST	Strip
SR	Syringe
ТВ	Tube
VL	Vial

For specific examples of this field, go to GPPC File Packaging Field Examples.

#### **Generic Product Identifier**

This is a 14-character field.

The Generic Product Identifier (GPI) categorizes drug products by a hierarchical therapeutic classification scheme. The GPI defines pharmaceutically equivalent drug products that are identical in:

- active ingredient(s)
- dosage form
- route
- strength or concentration

For specific examples of this field, go to GPPC File Packaging Field Examples.

For more information, see "Generic Product Identifier" in Chapter 2.

#### Reserve

This is a 14-character field.

The Reserve field is an unused field that may be used at a future date.

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#### **Transaction CD**

This is a 1-character field.

The Transaction CD indicates the file activity that last occurred for a record. Valid Values:

Value	Description
Α	Add
С	Change
D	Delete
þ/	No Change

	te All Transaction CDs are blank for Total Database.
--	--

### **Last Change Date**

This is an 8-digit numeric field.

The Last Change Date identifies the most recent build date any field in the record was changed.

This date is in Gregorian format.

## **Error Correct File**

#### (MF2ERR)

The Error Correct File contains the unique key and data element code of the field that has been "error corrected."

Error corrections occur if the data associated with a drug product is incorrect, either through a data entry error or through inaccurate or retracted information received directly from the manufacturer. For example, sometimes a manufacturer will inform Wolters Kluwer Clinical Drug Information of a price change which is output. Later the manufacturer may retract the price. Correct processing of the Error Correct File enables the end-user to detect these conditions and update their database accordingly.

Note	The Error Correct File is present only in an Incremental Update when an		
error correction has been made.			

Documentation Manual 4-63 Published: 11/11 Revised: 04/18 The Error Correct File contains the following data elements:

Code	Data Element Name	Record Position	Type/Length	Picture
K001	Key Identifier	1-1	C/1	Χ
K002	Unique Key	2-20	C/19	X(19)
K021	Data Element Code	21-24	C/4	X(4)
K025	Data Element Length	25-27	N/3	9(3)
K028	Reserve	28-32	C/5	X(5)

**Note** The shaded rows represent the unique key into the file.

## **Key Identifier**

This is a 1-character field.

The Key Identifier identifies the Unique Key [Data Element Code K002] for the record.

#### Valid Values:

Value	Description	
1	Drug Descriptor Identifier	
2	NDC-UPC-HRI	
3	NDC-UPC-HRI and Price Type	

### Example:

Key Identifier	Unique Key	Data Element Code	Data Element Length
2 (NDC-UPC-HRI)	50428207688	H023	8
3 (NDC-UPC-HRI and Price Type)	50428207688A	M021	11

# **Unique Key**

This is a 19-character field.

The Unique Key contains the actual value that was used to update the error corrected information.

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### Example:

Key Identifier	Unique Key	Data Element Code	Data Element Length
2 (NDC-UPC-HRI)	50428207688	H023	8
3 (NDC-UPC-HRI and Price Type)	50428207688A	M021	11

### **Data Element Code**

This is a 4-character field.

The Data Element Code identifies the record and position of the field within the file which was error corrected.

#### Example:

Key Identifier	Unique Key	Data Element Code	Data Element Length
2 (NDC-UPC-HRI)	50428207688	H023	8
3 (NDC-UPC-HRI and Price Type)	50428207688A	M021	11

## **Data Element Length**

This is a 3-digit numeric field.

The Data Element Length indicates the length of the field which was error corrected.

#### Example:

Key Identifier	Unique Key	Data Element Code	Data Element Length
2 (NDC-UPC-HRI)	50428207688	H023	8
3 (NDC-UPC-HRI and Price Type)	50428207688A	M021	11

### Reserve

This is a 5-character field.

The Reserve field is an unused field that may be used at a future date.

## **GPPC Price File**

#### (MF2GPR)

The GPPC Price File provides AAWPs and GEAPs for drug products, when applicable.

The GPPC Price File may contain multiple prices associated with a specific GPPC. There is one occurrence for a GPPC and GPPC Price Code, but not every GPPC or GPPC and GPPC Price Code has a record in this file. There may be zero, one, or many pricing records for a GPPC; however, there can be no more than one occurrence for a given GPPC and GPPC Price Code combination.

The GPPC Price File contains the following data elements:

Code	Data Element Name	Record Position	Type/Length	Picture
L001	Generic Product Packaging Code	1-8	C/8	X(8)
L009	GPPC Price Code	9-9	C/1	Х
L010	Effective Date	10-17	N/8	9(8)
L018	Unit Price	18-28	N/11	9(5)V9(6)
L029	Reserve	29-55	C/27	X(27)
L056	Transaction CD	56-56	C/1	X(1)
L057	Last Change Date	57-64	N/8	9(8)

**Note** The shaded rows represent the unique key into the file.

## **Generic Product Packaging Code**

This is an 8-character field

The Generic Product Packaging Code (GPPC) identifies unique combinations of the following fields:

Data Element Name	Data Element Code
Generic Product Identifier	J028
Package Description Code	J026
Package Size	J009
Package Size Unit of Measure	J018

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Data Element Name	Data Element Code
Package Quantity	J020
Unit-Dose/Unit-of-Use Package Code	J025

### **GPPC Price Code**

This is a 1-character field.

The GPPC Price Code indicates the type of pricing in the Unit Price [Data Element Code L018] and GPPC Eff Date [Data Element Code L010] fields.

#### Valid Values:

Value	Description
1	Average AWP (AAWP)
2	Generic Equivalent AWP (GEAP)

At the time when a generic product no longer has therapeutic equivalent drug products or the number of manufacturers is insufficient to calculate an average, a record with a GPPC Price Code of 2 and a price of 00000.000000 is represented in the output on Incremental Updates. After that time, this combination of GPPC and GPPC Price Code continues to be represented in the output on Total Databases with a price of 00000.000000 or until an AAWP or GEAP is calculated again.

#### **Effective Date**

This is an 8-digit numeric field.

The Effective Date is the date the GPPC Unit Price was computed. If a price has not changed since the previous calculation, the date reflects that previous calculation.

This date is in Gregorian (YYYYMMDD) format.

#### **Unit Price**

This is an 11-digit numeric field.

The GPPC Unit Price is defined by the GPPC Price Code [Data Element Code L009].

Note	This field outputs as 00000000000 if the unit price is greater than \$99,999.

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#### Reserve

This is a 27-character field.

The Reserve field is an unused field that may be used at a future date.

#### **Transaction CD**

This is a 1-character field.

The Transaction CD indicates the file activity that last occurred for a record.

#### Valid Values:

Value	Description
A	Add
С	Change
D	Delete
b'	No Change

saction CDs are blank for Total Database.
---

## **Last Change Date**

This is an 8-digit numeric field.

The Last Change Date identifies the most recent build date any field in the record was changed.

This date is in Gregorian format.

## **NDC Price File**

#### (MF2PRC)

The NDC Price File provides, if available, the current AWP, DP, CMS FUL, and WAC prices and their price effective dates.

The NDC Price File may contain multiple records for a specific NDC-UPC-HRI. There will be one occurrence for a NDC-UPC-HRI and a selected Price Code, but not every NDC-UPC-HRI will have all Price Codes in this file.

4-68 MED-File v2 Published: 11/11 Revised: 04/18 The NDC Price File contains the following data elements:

Code	Data Element Name	Record Position	Type/Length	Picture
M001	NDC-UPC-HRI	1-11	C/11	X(11)
M012	Price Code	12-12	C/1	Х
M013	Price Effective Date	13-20	N/8	9(8)
M021	Unit Price	21-31	N/11	9(5)V9(6)
M032	Unit Price - Extended	32-44	N/13	9(8)V9(5)
M045	Package Price	45-54	N/10	9(8)V9(2)
M055	AWP Indicator Code	55-55	C/1	Х
M056	Transaction CD	56-56	C/1	Х
M057	Last Change Date	57-64	N/8	9(8)

#### **NDC-UPC-HRI**

This is an 11-character field.

NDCs, UPCs, and HRIs are 10-character codes used to identify drug products. Surgical supplies and nonprescription drug products may have an NDC and an HRI or UPC according to the standards set forth by the Uniform Product Code Council, Inc. These codes are converted to eleven characters according to NCPDP standards.

#### **Price Code**

The Price Code indicates the type of price in the record.

#### Valid Values:

Value	Description
Α	AWP
D	DP
Н	HCFA FFP
U	HCFA FFP for unit dose items
W	WAC

Note	In this file, "HCFA FFP" represents the Centers for Medicare and Medicaid
	Services Federal Upper Limit (CMS FUL).

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#### **Price Effective Date**

The Price Effective Date represents the effective date of the price.

The Price Effective Date is in Gregorian format.

#### **Unit Price**

This is an 11-digit numeric field.

The Unit Price represents the price per each unit (tablet, capsule, lozenge, suppository, etc.), gram, or milliliter, as defined by the Package Size Unit of Measure.

The Unit Price is computed by dividing the Package Price by the product of the Package Size multiplied by the Package Quantity. The cost of the prescription can be calculated by multiplying the Unit Price by the quantity dispensed.

In the case where dry injectable products may be reconstituted to variable volumes, this price represents the price per single dry vial, ampule, or syringe.

Note

This field outputs as *000000000000* if the unit price is greater than \$99,999.

#### **Unit Price - Extended**

This is a 13-digit numeric field.

The Unit Price - Extended is similar to the Unit Price field in that it represents the price per each unit (tablet, capsule, lozenge, suppository, etc.), gram, or milliliter, as defined by the Package Size Unit of Measure.

The Unit Price - Extended is computed by dividing the Package Price by the product of the Package Size multiplied by the Package Quantity. The cost of the prescription can be calculated by multiplying the Unit Price - Extended by the quantity dispensed.

4-70 MED-File v2 Published: 11/11 Revised: 04/18 In the case where dry injectable products may be reconstituted to variable volumes, this price represents the price per single dry vial, ampule, or syringe.

Package Price	
(Package Size * Package	= Unit Price -Extended
Quantity)	

Note

The Unit Price - Extended field allows for additional positions to the left of the decimal point that are not available in the Unit Price field. When the Unit Price exceeds \$99,999, the Unit Price field will be output as 00000000000 and only the Unit Price - Extended will be populated.

### **Package Price**

This is a 10-digit numeric field.

The Package Price represents the price for the entire package of the item. The Package Price is converted to Unit Price by dividing the Package Price by the product of the Package Size multiplied by the Package Quantity. The cost of the prescription can be calculated by multiplying the Unit Price by the quantity dispensed.

In the case where dry injectable products may be reconstituted to variable volumes, this price represents the price per single dry vial, ampule, or syringe.

#### **AWP Indicator Code**

The AWP Indicator Code is a proprietary Wolters Kluwer Clinical Drug Information concept that indicates how the AWP was obtained by Wolters Kluwer Clinical Drug Information.

The current values are:

Value	Description
Α	Mark-up < 1.20 mfr. WAC or DP
L	Std. mark-up of 1.20 mfr. WAC or DP
S	Mfr. suggested AWP
K	Adj. std. mark-up of 1.20 mfr. WAC or DP
М	Std. mark-up of 1.25 mfr. WAC or DP

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Note

The codes, descriptions, and definitions above reflect Wolters Kluwer Clinical Drug Information's current AWP editorial policies. This information may have changed over time with announced changes in our AWP editorial policies. Please refer to current and historical editorial polices or contact Wolters Kluwer Clinical Drug Information Customer Support if you have questions regarding use of these codes, descriptions, and definitions.

The AWP Indicator Code is used as follows:

- Prior to September 26, 2009, AWP Indicator Codes of A, S, and M were in use.
- AWP Indicator Code K was used to make one-time adjustments effective September 26, 2009.
- As of September 27, 2009, AWP Indicator Codes of A, S, and L are used.

### **Transaction CD**

This is a 1-character field.

The Transaction CD indicates the file activity that last occurred for a record.

#### Valid Values:

Value	Description
Α	Add
С	Change
D	Delete
p,	No Change

Note All Transaction CDs are blank for Total Database.

## **Last Change Date**

This is an 8-digit numeric field.

The Last Change Date identifies the most recent build date any field in the record was changed.

This date is in Gregorian format.

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## **Modifier File**

#### (MF2MOD)

The Modifier File contains codes and descriptions of supplemental information not included in the package and product description but useful to identify packaging and product types.

Each Modifier Code record is linked to zero, one, or many NDC Modifier File records through the Modifier Code.

The Modifier File contains the following data elements:

Code	Data Element Name	Record Position	Type/Length	Picture
N001	Modifier Code	1-6	C/6	X(6)
N007	Modifier Description	7-31	C/25	X(25)
N032	Reserve	32-55	C/24	X(24)
N056	Transaction CD	56-56	C/1	Х
N057	Last Change Date	57-64	N/8	9(8)

**Note** The shaded row represents the unique key into the file.

#### **Modifier Code**

This is a 6-character field.

Modifier Codes describe supplemental information not included in any other field but can be used to identify unique product or packaging types. Modifier Codes are available in the NDC Modifier File. Modifier Codes include information such as needle length and gauge, vial type (for example, ADD-Vantage and pintop), product flavors, and more.

Effective March 1, 1018, compounded products from outsourcing facilities will have only one product modifier, "Compounded Product". All other product modifiers will not be applicable for compounded products from outsourcing facilities.

The structure of the Modifier Code and the Modifier Type are illustrated below.

Modifier Codes are comprised of three two-character subsets. The first subset defines the Modifier Type.

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#### Valid Values:

Value	Modifier Type
AA	Package Modifiers
ВВ	Product Modifiers
TT	Trademark Modifiers

The first and second subsets define the Modifier Type and Modifier Category.

#### Examples of Package Modifiers include:

Value	Modifier Category
AA AA	Vial Sizes
AA AB	Parenteral Packaging Descriptions
AA AC	Needle Lengths and Gauges
AA AD	Non-Parenteral Packaging Descriptions
AA AE	Neonatal/Pediatric Packaging
AA AF	Package Size
AA AG	Item Size Description

#### **Examples of Product Modifiers include:**

Value	Modifier Category
BB AA	Colors
BB AB	Flavors
BB AC	Base Types
BB AD	Dosage Forms
BB AE	Shapes
BB AF	Free Descriptions (such as Dye Free and Alcohol Free)
BB AG	Fragrance

#### Note

Colors, Flavors, Base Types, Dosage Forms, Shapes, and Free Descriptions are included when multiple original drug products are available. These descriptions differentiate generic drug products mimicking original drug products. This information is not included in the GPI. A Modifier Code is only present when relevant to the drug product. A color Product Modifier is not present if two colors are noted for the same NDC-UPC-HRI.

#### Examples of Trademark Modifiers include:

Value	Category
TT AA	Trademark Packaging Terms
TT AB	Trademark Dosage Forms

4-74 MED-File v2 Published: 11/11 Revised: 04/18 The first, second, and third subsets define the Modifier Type, Modifier Category, and specific Modifier Code within a category.

## **Modifier Description**

This is a 25-character field.

The Modifier Description describes what the Modifier Code [N001] represents.

#### Example

Modifier Code	Modifier Description
AAAA28	500 ML
AAAA73	2 CARTONS OF 30 EACH
AAAB38	W/LUER LOCK
AAAB9D	W/O DILUENT
AAABN3	PRECISIONGLIDE NEEDLE
AAAC50	25G X 5/8
BBAAER	WHITE/PURPLE
BBAB96	CHERRY-VANILLA
BBAC7P	NON-ALKALINE
BBAD37	SOFTGEL(S)
BBAE23	RECTANGULAR
BBAF51	TALK FREE
BBAI01	MEDICAL FOOD
BBAI03	AUTHORIZED GENERIC
TTAA64	CONVENIENCE PACK
TTAAD3	AMBU-FLEX III
TTAABN4	DUOTAB

For a complete list of Modifier Codes and Modifier Descriptions, refer to the contents of the Modifier File.

#### Reserve

This is a 24-character field.

The Reserve field is an unused field that may be used at a future date.

#### **Transaction CD**

This is a 1-character field.

The Transaction CD indicates the file activity that last occurred for a record.

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#### Valid Values:

Value	Description
А	Add
С	Change
D	Delete
b'	No Change

	Note	All Transaction CDs are blank for Total Database.
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## **Last Change Date**

This is an 8-digit numeric field.

The Last Change Date identifies the most recent build date any field in the record was changed.

This date is in Gregorian format.

## **NDC Modifier File**

#### (MF2NDCM)

The NDC Modifier File contains the NDC-UPC-HRI and the Modifier Codes associated with the NDC-UPC-HRI. These Modifier Codes can be used to provide additional descriptive information or to create a nine-character GPPC.

Note	For more information regarding creating this nine-character GPPC, see
	Chapter 5: Applications.

There may be zero, one, or many Modifier Codes associated to an NDC-UPC-HRI.

The NDC Modifier File contains the following data elements:

Code	Data Element Name	Record Position	Type/Length	Picture
O001	NDC-UPC-HRI	1-11	C/11	X(11)
0012	Modifier Code	12-17	C/6	X(6)
0018	Reserve	18-23	C/6	X(6)
O024	Transaction CD	24-24	C/1	Х
O025	Last Change Date	25-32	N/8	9(8)

4-76 MED-File v2 Published: 11/11 Revised: 04/18 Note

The shaded rows represent the unique key into the file.

#### NDC-UPC-HRI

This is an 11-character field.

NDCs, UPCs, and HRIs are 10-character codes used to identify drug products. Surgical supplies and nonprescription drug products may have an NDC, and an HRI or UPC according to the standards set forth by the Uniform Product Code Council, Inc. These codes are converted to eleven characters according to NCPDP standards.

#### **Modifier Code**

This is an 6-character field.

Modifier Codes describe supplemental information not included in any other field but can be used to identify unique product or packaging types. Modifier Codes are available in the NDC Modifier File. Modifier Codes include information such as needle length and gauge, vial type (for example, ADD-Vantage and pintop), product flavors, and more.

The structure of the Modifier Code and the Modifier Type are illustrated below.

Modifier Codes are comprised of three two-character subsets. The first subset defines the Modifier Type.

#### Valid Values:

Value	Modifier Type
AA	Package Modifiers
ВВ	Product Modifiers
TT	Trademark Modifiers

The first and second subsets define the Modifier Type and Modifier Category.

#### Examples of Package Modifiers include:

Value	Modifier Category
AA AA	Vial Sizes
AA AB	Parenteral Packaging Descriptions
AA AC	Needle Lengths and Gauges
AA AD	Non-Parenteral Packaging Descriptions

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Value	Modifier Category
AA AE	Neonatal/Pediatric Packaging
AA AF	Package Size
AA AG	Item Size Description

#### **Examples of Product Modifiers include:**

Value	Modifier Category
BB AA	Colors
BB AB	Flavors
BB AC	Base Types
BB AD	Dosage Forms
BB AE	Shapes
BB AF	Free Descriptions (such as Dye Free and Alcohol Free)
BB AG	Fragrance

#### Note

Colors, Flavors, Base Types, Dosage Forms, Shapes, and Free Descriptions are included when multiple original drug products are available. These descriptions differentiate generic drug products mimicking original drug products. This information is not included in the GPI. A Modifier Code is only present when relevant to the drug product. A color Product Modifier is not present if two colors are noted for the same NDC-UPC-HRI.

#### Examples of Trademark Modifiers include:

Modifier Code	Modifier Description
TT AA	Trademark Packaging Terms
TT AB	Trademark Dosage Forms

The first, second, and third subsets define the Modifier Type, Modifier Category, and specific Modifier Code within a category.

#### The Package Modifiers Describing Vial Sizes include:

Modifier Code	Modifier Description
AA AA 01	1 ML
AA AA 02	1.5 ML

#### Reserve

This is a 6-character field.

The Reserve field is an unused field that may be used at a future date.

#### **Transaction CD**

This is a 1-character field.

The Transaction CD indicates the file activity that last occurred for a record.

#### Valid Values:

Value	Description
Α	Add
С	Change
D	Delete
b'	No Change

|--|--|--|--|

### **Last Change Date**

This is an 8-digit numeric field.

The Last Change Date identifies the most recent build date any field in the record was changed.

This date is in Gregorian format.

# **SDI Drug Name File**

#### (MF2DRGNM)

The SDI Drug Name File contains the fields associated with a drug name. Specific drug name description data resides in the Description File (MF2DESC). The SDI Drug Name File includes additional historical concepts that are not reflected in the Drug Name File.

The SDI Drug Name File contains the following data elements:

Code	Data Element Name	Record Position	Type/Length	Picture
P001	Concept Type	1-5	N/5	9(5)
P006	Country Code	6-7	N/2	9(2)
P008	Concept ID	8-17	N/10	9(10)
P018	Transaction CD	18-18	C/1	Х
P019	Name Type	19-19	C/1	Х
P020	Status	20-20	N/1	9(1)

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Code	Data Element Name	Record Position	Type/Length	Picture
P021	Link Value	21-30	N/10	9(10)
P031	Link Date	31-38	N/8	YYYYMMDD
P039	Reserve	39-48	C/10	X(10)

## **Concept Type**

This is a 5-digit numeric field.

The Concept Type defines the type of concept that is represented by the Concept ID. Specific SDI Drug Name description data resides in the Description File (MF2DESC).

#### Valid Values:

Value	Description
00001	Drug Name
00002	Routed Drug
00003	Routed Dose Form Drug
00004	Dispensable Drug
00005	GPI
00006	GPPC5
00007	NDC-UPC-HRI
00008	Route
00009	Dose Form
00221	Dose Form Drug
00222	Strength-Strength UOM

## **Country Code**

This is a 2-digit numeric field.

The Country Code represents the country to which a Drug Name is specific.

Note	01 (USA) is the only value in use at this time.	
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### **Concept ID**

This is a 10-digit numeric field.

The Concept ID identifies the Drug Name.

#### **Transaction CD**

This is a 1-character field.

The Transaction CD indicates the file activity that last occurred for a record.

The current values are:

Value	Description
Α	Add
С	Change
D	Delete
p,	No Change

Note	All Transaction CDs are blank for Total Databases.

## **Name Type**

This is a 1-character field.

The Name Type identifies whether the Drug Name is a brand name, generic or trademarked drug name.

Valid Values:

Value	Description
1	Trademarked
2	Brand Name
3	Generic

#### **Status**

This is a 1-digit numeric field.

The Status defines the current state of the drug name concept.

#### Valid Values:

Value	Description	Abbreviation
1	Active Concept with Active Associated Products	Active w/Prod
2	Active w/Assc Prd Inactive <48 Months	Active w/Inact
3	Inactive w/Assc Prd Inactive >48 Months	Inactive w/Prd
4	Inactive w/no Assc Products	Inac w/o Prd

Note	A Status value of 1 or 2 does not imply that a corresponding NDC-UPC-HRI
	with this drug name exists in the NDC File.

#### **Link Value**

This is a 10-digit numeric field.

The Link Value identifies the new Concept ID that replaces the Concept ID in this record.

Note	The Link Value for this file is not in use at this time. For more information,
	go to Chapter 5, "Applications".

### **Link Date**

This is an 8-digit numeric field.

The Link Date represents the date the Concept ID was replaced by the Link Value.

Note	The Link Date for this file is not in use at this time. For more information,
	go to Chapter 5, "Applications".

#### Reserve

This is a 10-character field.

The Reserve field is an unused field that may be used at a future date.

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# **Routed Drug File**

#### (MF2RTDRG)

The Routed Drug File contains the fields associated with a drug and its route of administration. Specific Routed Drug description data resides in the Description File (MF2DESC). The Routed Drug File includes additional historical concepts that are not reflected in the Drug Name File.

For more information, go to Chapter 2, "Editorial Policies".

The Routed Drug File contains the following data elements:

Code	Data Element Name	Record Position	Type/Length	Picture
Q001	Concept Type	1-5	N/5	9(5)
Q006	Country Code	6-7	N/2	9(2)
Q008	Concept ID	8-17	N/10	9(10)
Q018	Transaction CD	18-18	C/1	X(1)
Q019	Drug Name ID	19-28	N/10	9(10)
Q029	Route ID	29-33	N/5	9(5)
Q034	Status	34-34	N/1	9(1)
Q035	Link Value	35-44	N/10	9(10)
Q045	Link Date	45-52	N/8	YYYYMMDD
Q053	Reserve	53-80	C/28	X(28)

Note	The shaded rows represent the unique key into the file.
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## **Concept Type**

This is a 5-digit numeric field.

The Concept Type defines the type of concept that is represented by the Concept ID.

#### Valid Values:

Value	Description
00001	Drug Name
00002	Routed Drug
00003	Routed Dose Form Drug
00004	Dispensable Drug
00005	GPI
00006	GPPC5

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Value	Description
00007	NDC-UPC-HRI
80000	Route
00009	Dose Form
00221	Dose Form Drug
00222	Strength-Strength UOM

<b>Note</b> 00002 (Routed Drug) is the only value used in the Routed Drug File.	
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## **Country Code**

This is a 2-digit numeric field.

The Country Code represents the country to which a Routed Drug is specific.

Note	01 (USA) is the only value in use at this time.	
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### **Concept ID**

This is a 10-digit numeric field.

The Concept ID identifies the Routed Drug.

### **Transaction CD**

This is a 1-character field.

The Transaction CD indicates the file activity that last occurred for a record.

The current values are:

Value	Description
Α	Add
С	Change
D	Delete
b⁄	No Change

Note	All Transaction CDs are blank for Total Databases.	
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### **Drug Name ID**

This is a 10-digit numeric field.

The Drug Name ID is a Concept ID representing a Drug Name in the SDI Drug Name File. A description of this value is available in the Description File (MF2DESC).

#### **Route ID**

This is a 5-digit numeric field.

The Route ID is a Concept ID representing a Route in the Route File. A description of this value is available in the Description File (MF2DESC).

#### **Status**

This is a 1-digit numeric field.

The Status defines the current state of the routed drug concept.

#### Valid Values:

Value	Description	Abbreviation
1	Active Concept with Active Associated Products	Active w/Prod
2	Active w/Assc Prd Inactive <48 Months	Active w/Inact
3	Inactive w/Assc Prd Inactive >48 Months	Inactive w/Prd
4	Inactive w/no Assc. Products	Inac w/o Prd

Note	A Status of 1 or 2 does not imply that a corresponding NDC-UPC-HRI with this
	drug name and route exists in the NDC File.

#### **Link Value**

This is a 10-digit numeric field.

The Link Value identifies the new Concept ID that replaces the Concept ID in this record.

Note	The Link Value for this file is not in use at this time. For more information,
	go to Chapter 5, "Applications".

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#### **Link Date**

This is an 8-digit numeric field.

The Link Date represents the date the Concept ID was replaced by the Link Value.

Note	The Link Date for this file is not in use at this time. For more information,
	go to Chapter 5, "Applications".

#### Reserve

This is a 28-character field.

The Reserve field is an unused field that may be used at a future date.

# **Drug-Dose Form File**

#### (MF2DFDRG)

The Drug-Dose Form File contains the fields associated with a drug and its dosage form. Specific Dosage Form description data resides in the Description File (MF2DESC). The Drug-Dose Form File includes additional historical concepts that are not reflected in the Drug Name File.

The Drug-Dose Form File contains the following data elements

Code	Data Element Name	Record Position	Type/Length	Picture
R001	Concept Type	1-5	N/5	9(5)
R006	Country Code	6-7	N/2	9(2)
R008	Concept ID	8-17	N/10	9(10)
R018	Transaction CD	18-18	C/1	X(1)
R019	Drug Name ID	19-28	N/10	9(10)
R029	Dose Form ID	29-33	N/5	9(5)
R034	Status	34-34	N/1	9(1)
R035	Link Value	35-44	N/10	9(10)
R045	Link Date	45-52	N/8	YYYYMMDD
R053	Reserve	53-80	C/28	X(28)

**Note** The shaded rows represent the unique key into the file.

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## **Concept Type**

This is a 5-digit numeric field.

The Concept Type defines the type of concept that is represented by the Concept ID.

#### Valid Values:

Value	Description
00001	Drug Name
00002	Routed Drug
00003	Routed Dose Form Drug
00004	Dispensable Drug
00005	GPI
00006	GPPC5
00007	NDC-UPC-HRI
80000	Route
00009	Dose Form
00221	Dose Form Drug
00222	Strength-Strength UOM

Note	00221 (Dose Form Drug) is the only value used in the Drug-Dose Form File.	
1,000	3022 · (2000 · 0 2. ug) is the only value used in the 2. ug 2000 · 0	

## **Country Code**

This is a 2-digit numeric field.

The Country Code represents the country to which a Dose Form Drug is specific.

# **Concept ID**

This is a 10-digit numeric field.

The Concept ID identifies the Dose Form Drug.

### **Transaction CD**

This is a 1-character field.

The Transaction CD indicates the file activity that last occurred for a record.

The current values are:

Value	Description
Α	Add
С	Change
D	Delete
b'	No Change

Note All Transaction CDs are blank for Total Databases.	
---	--

### **Drug Name ID**

This is a 10-digit numeric field.

The Drug Name ID is a Concept ID representing a Drug Name in the Drug Name File. A description of this value is available in the Description File (MF2DESC).

### **Dose Form ID**

This is a 5-digit numeric field.

The Dose Form ID is a Concept ID representing a Dose Form in the Dose Form File. A description of this value is available in the Description File (MF2DESC).

#### **Status**

This is a 1-digit numeric field.

The Status defines the current state of the dose form drug concept.

#### Valid Values:

Value	Description	Abbreviation
1	Active Concept with Active Associated Products	Active w/Prod
2	Active w/Assc Prd Inactive <48 Months	Active w/Inact
3	Inactive w/Assc Prd Inactive >48 Months	Inactive w/Prd
4	Inactive w/no Assc. Products	Inac w/o Prd

**Note** A Status value of 1 or 2 does not imply that a corresponding NDC-UPC-HRI with this drug, name, and dosage form exists in the NDC File.

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### **Link Value**

This is a 10-digit numeric field.

The Link Value identifies the new Concept ID that replaces the Concept ID in this record.

Note	The Link Value for this file is not in use at this time. For more information,
	go to Chapter 5, "Applications".

### **Link Date**

This is an 8-digit numeric field.

The Link Date represents the date the Concept ID was replaced by the Link Value.

Note	The Link Date for this file is not in use at this time. For more information,
	go to Chapter 5, "Applications".

#### Reserve

This is a 28-character field.

The Reserve field is an unused field that may be used at a future date.

# **Routed Drug Form File**

#### (MF2RTDF)

The Routed Drug Form File contains the fields associated with a drug and its route of administration and dosage form. Specific Routed Dose Form description data resides in the Description File (MF2DESC). The Routed Drug Form File includes additional historical concepts that are not reflected in the Drug Name File.

The Routed Drug Form File contains the following data elements:

Code	Data Element Name	Record Position	Type/Length	Picture
S001	Concept Type	1-5	N/5	9(5)
S006	Country Code	6-7	N/2	9(2)
S008	Concept ID	8-17	N/10	9(10)

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Code	Data Element Name	Record Position	Type/Length	Picture
S018	Transaction CD	18-18	C/1	X
S019	Routed Drug ID	19-28	N/10	9(10)
S029	Dose Form ID	29-33	N/5	9(5)
S034	Status	34-34	N/1	9(1)
S035	Link Value	35-44	N/10	9(10)
S045	Link Date	45-52	N/8	YYYYMMDD
S053	Reserve	53-80	C/28	X(28)

Note The shaded rows represent the unique key into the file.	
--	--

# **Concept Type**

This is a 5-digit numeric field.

The Concept Type defines the type of concept that is represented by the Concept ID.

### Valid Values:

Value	Description
00001	Drug Name
00002	Routed Drug
00003	Routed Dose Form Drug
00004	Dispensable Drug
00005	GPI
00006	GPPC5
00007	NDC-UPC-HRI
00008	Route
00009	Dose Form
00221	Dose Form Drug
00222	Strength-Strength UOM

Note	00003 (Routed Dose Form Drug) is the only value used in the Routed Drug
	Form File.

# **Country Code**

This is a 2-digit numeric field.

4-90 MED-File v2 Published: 11/11 Revised: 04/18 The Country Code represents the country to which a Routed Dose Form Drug is specific.

Note 01 (USA) is the only value in use at this time.

### **Concept ID**

This is a 10-digit numeric field.

The Concept ID identifies the Routed Dose Form Drug.

#### **Transaction CD**

This is a 1-character field.

The Transaction CD indicates the file activity that last occurred for a record.

The current values are:

Value	Description
Α	Add
С	Change
D	Delete
p,	No Change

<b>Note</b> All Iransaction CDs are blank for lotal Databases.	Note	All Transaction CDs are blank for Total Databases.	
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# **Routed Drug ID**

This is a 10-digit numeric field.

The Routed Drug ID is a Concept ID representing a Routed Drug in a Routed Drug File. A description of this value is available in the Description File (MF2DESC).

#### **Dose Form ID**

This is a 5-digit numeric field.

The Dose Form ID is a Concept ID representing a Dose Form in the Dose Form File. A description of this value is available in the Description File (MF2DESC).

### **Status**

This is a 1-digit numeric field.

The Status defines the current state of the routed dose form drug concept.

#### Valid Values:

Value	Description	Abbreviation
1	Active Concept with Active Associated Products	
2	Active w/Assc Prd Inactive <48 Months	Active w/Inact
3	Inactive w/Assc Prd Inactive >48 Months	Inactive w/Prd
4	Inactive w/no Assc. Products	Inac w/o Prd

Note	A Status value of 1 or 2 does not imply that a corresponding NDC-UPC-HRI
	with this drug name, route, and dosage form exists in the NDC File.

### **Link Value**

This is a 10-digit numeric field.

The Link Value identifies the new Concept ID that replaces the Concept ID in this record.

Note	The Link Value for this file is not in use at this time. For more information,
	go to Chapter 5, "Applications".

### **Link Date**

This is an 8-digit numeric field.

The Link Date represents the date the Concept ID was replaced by the Link Value.

Note	The Link Date for this file is not in use at this time. For more information,
	go to Chapter 5, "Applications".

### Reserve

This is a 28-character field.

4-92 MED-File v2 Published: 11/11 Revised: 04/18 The Reserve field is an unused field that may be used at a future date.

# **Dispensable Drug File**

### (MF2DRG)

The Dispensable Drug File contains the fields associated with the Dispensable Drug (DDID). Specific Dispensable Drug description data resides in the Description File (MF2DESC). The Dispensable Drug File includes additional historical concepts that are not reflected in the Drug Name File.

Note	The Dispensable Drug and the Drug Descriptor are one and the same. The
	terms may be used interchangeably in this and other Wolters Kluwer Clinical
	Drug Information documents.

The Dispensable Drug File contains the following data elements:

Code	Data Element Name	Record Position	Type/Length	Picture
T001	Concept Type	1-5	N/5	9(5)
T006	Country Code	6-7	N/2	9(2)
T008	Concept ID	8-17	N/10	9(10)
T018	Transaction CD	18-18	C/1	Х
T019	Routed Drug ID	19-28	N/10	9(10)
T029	Dose Form ID	29-33	N/5	9(5)
T034	Strength	34-48	C/15	X(15)
T049	Strength Unit of	49-63	C/15	X(15)
	Measure			
T064	Name Source	64-64	N/1	9(1)
T065	Device Flag	65-65	N/1	9(1)
T066	Status	66-66	N/1	9(1)
T067	Link Value	67-76	N/10	9(10)
T077	Link Date	77-84	N/8	YYYYMMDD
T085	Routed Drug Form ID	85-94	N/10	9(10)
T095	Drug-Dose Form ID	95-104	N/10	9(10)
T105	Strength-Strength UOM ID	105-114	N/10	9(10)
T115	Reserve	115-144	C/30	X(30)

Note The shaded rows represent the unique key into the file.
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Revised: 04/18

## **Concept Type**

This is a 5-digit numeric field.

The Concept Type defines the type of concept that is represented by the Concept ID.

#### Valid Values:

Value	Description	
00001	Drug Name	
00002	Routed Drug	
00003	Routed Dose Form Drug	
00004	Dispensable Drug	
00005	GPI	
00006	GPPC5	
00007	NDC-UPC-HRI	
00008	Route	
00009	Dose Form	
00221	Dose Form Drug	
00222	Strength-Strength UOM	

**Note** 00004 (Dispensable Drug) is the only value used in the Dispensable Drug File.

# **Country Code**

This is a 2-digit numeric field.

The Country Code represents the country to which a Dispensable Drug is specific.

Note 01 (USA) is the only value in use at this time.

# **Concept ID**

This is a 10-digit numeric field.

The Concept ID identifies the Dispensable Drug.

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In the Dispensable Drug File, the DDID is defined as a 10-digit number. In the Drug Name File, the DDID is defined as a 6-digit number. They represent the same drug concept. For example, Concept ID "0000000232" in the Dispensable Drug File and Drug Descriptor Identifier "000232" in the Drug Name File both identify "Accupril Oral Tablet 10 MG".

### **Transaction CD**

This is a 1-character field.

The Transaction CD indicates the file activity that last occurred for a record.

The current values are:

Value	Description
Α	Add
С	Change
D	Delete
p,	No Change

Note	All Transaction CDs are blank for Total Databases.	
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## **Routed Drug ID**

This is a 10-digit numeric field.

The Routed Drug ID is a Concept ID representing a Routed Drug in the Routed Drug File. A description of this value is available in the Description File (MF2DESC).

### **Dose Form ID**

This is a 5-digit numeric field.

The Dose Form ID is a Concept ID representing a Dose Form in the Dose Form File. A description of this value is available in the Description File (MF2DESC).

## Strength

This is a 15-character field.

The Strength is a character representation of the product's ingredient strength. When combined with the Strength Unit of Measure, it represents the dosage strength as provided by the manufacturer.

## **Strength Unit Of Measure**

This is a 15-character field.

The Strength Unit Of Measure, when combined with the Strength, represents the dosage strength as provided by the manufacturer.

#### Example\*:

Strength	Description	Strength	Description
%	Percent	MG	Milligram
AHFU	Antihemophilic factor unit	MG/HR	Milligram/hour
GM	Gram	MG/ML	Milligram/milliliter
GM/ML	Gram/milliliter	MINIM	Minim
UNIT	International unit	MMOLE	Millimole
UNIT/ML	International unit/ milliliter	MMOLE/ML	Millimole/milliliter
MCG	Microgram	MU	Million units
MCG/ML	Microgram/milliliter	SQ CM	Square centimeter
MEQ	Milliequivalent	UNIT	Unit
MEQ/L	Milliequivalent/liter	UNIT/GM	Unit/gram
MEQ/ML	Milliequivalent/ milliliter	UNIT/ML	Unit/milliliter

Note	* Due to the dynamic nature of these data, additional values may be added without notice.		
Note	In the Dispensable Drug File, the Strength Unit of Measure is defined as a 15-character field. In the Drug Name File, the Strength Unit of Measure is defined as a 10-character field. They both represent the same concept. The data within these fields is the same.		

#### Name Source

This is a 1-digit numeric field.

4-96 MED-File v2 Published: 11/11 Revised: 04/18 The Name Source field identifies whether the name came from the Generic Product, the Product, or both the Generic Product and the Product.

#### Valid Values:

Value	Description
0	Generic
1	Product
2	Generic Product & Product

# **Device Flag**

This is a 1-digit numeric field.

The Device Flag field indicates whether or not the Dispensable Drug is a device.

#### Valid Values:

Value	Description
0	Non Device
1	Device

### **Status**

This is a 1-digit numeric field.

The Status defines the current state of the Dispensable Drug concept.

#### Valid Values:

Value	Description	Abbreviation
1	Active Concept with Active Associated Products	Active w/Prod
2	Active w/Assc Prd Inactive <48 Months	Active w/Inact
3	Inactive w/Assc Prd Inactive >48 Months	Inactive w/Prd
4	Inactive w/no Assc. Products	Inac w/o Prd

Note	A Status value of 1 or 2 does not imply that a corresponding NDC-UPC-HRI
	for the Dispensable Drug exists in the NDC File.

# **Link Value**

This is a 10-digit numeric field.

The Link Value identifies the new Concept ID that replaces the Concept ID in this record.

**Note** The Link Value for this file is *currently* in use at this time. For more information, go to Chapter 5, "Applications".

### **Link Date**

This is an 8-digit numeric field.

The Link Date represents the date the Concept ID was replaced by the Link Value.

Note The Link Date for this file is *currently* in use at this time. For more information, go to Chapter 5, "Applications".

### **Routed Drug Form ID**

This is a 10-digit numeric field.

The Routed Drug Form ID is a Concept ID representing a Routed Drug Form in the Routed Drug Form File. A description of this value is available in the Description File (MF2DESC).

# **Drug-Dose Form ID**

This is a 10-digit numeric field.

The Drug-Dose Form ID is a Concept ID representing a drug and its dose form in the Drug-Dose Form File. A description of this value is available in the Description File (MF2DESC).

## Strength-Strength UOM ID

This is a 10-digit numeric field.

The Strength-Strength UOM ID is a Concept ID representing the combination of the strength and the strength unit of measure in the Strength-Strength Unit of Measure File. A description of this value is available in the Description File (MF2DESC).

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#### Reserve

This is a 30-character field.

The Reserve field is an unused field that may be used at a future date.

# **Description File**

#### (MF2DESC)

The Description File contains descriptions for the Concept IDs for the below files:

- SDI Drug Name File
- Routed Drug File
- Drug-Dose Form File
- Routed Dose Form File
- Dispensable Drug File
- Route File
- · Dose Form File
- Strength-Strength Unit of Measure File
- Drug Concept ID to Ingredient Set ID File

The Description File includes additional historical concepts that are not reflected in the Drug Name File. The Description File contains the following data elements:

Code	Data Element Name	Record Position	Type/Length	Picture
U001	Concept Type	1-5	N/5	9(5)
U006	Country Code	6-7	N/2	9(2)
U008	Concept ID	8-17	N/10	9(10)
U018	Type Code	18-18	N/1	N(1)
U019	Transaction CD	19-19	C/1	Х
U020	Description	20-269	C/250	X(250)
U270	Reserve	270-336	C/67	X(67)

**Note** The shaded rows represent the unique key into the file.

# **Concept Type**

This is a 5-digit numeric field.

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The Concept Type defines the type of concept that is represented by the Concept ID.

#### Valid Values:

Value	Description	
00001	Drug Name	
00002	Routed Drug	
00003	Routed Dose Form Drug	
00004	Dispensable Drug	
00005	GPI	
00006	GPPC5	
00007	IDC-UPC-HRI	
00008	Route	
00009	Dose Form	
00221	Dose Form Drug	
00222	Strength-Strength UOM	

Note	00005 (GPI), 00006 (GPPC), and 00007 (NDC-UPC-HRI) are currently not used
	in this file.

# **Country Code**

This is a 2-digit numeric field.

The Country Code represents the country to which a Concept Type, Concept ID, and Type Code are specific.

Note (	01 (USA) is the only value in use at this time.	
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# **Concept ID**

This is a 10-digit numeric field.

The Concept ID represents a specific concept for a Concept Type, Country Code, and Type Code.

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### Example:

Concept Type	Concept ID	Type Code	Description
1	26124	1	Zetia
Drug Name		Full Text Description	
1	26124	3	ZETIA
Drug Name		Capitalized Name	
2	26124	1	Thinlets GP Lancets (Does
Routed Drug		Full Text Description	not apply)
3	26124	1	Melatonin-Pyridoxine Oral
Routed Dose		Full Text Description	Tablet Extended Release
Form Drug			
4	26124	1	Chlorpheniramine-
Dispensable		Full Text Description	Phenylephrine Oral Syrup 1-
Drug			2.5 MG/5ML

# **Type Code**

This is a 1-digit numeric field.

The Type Code indicates the type of description in the record.

### Valid Values:

ID	Description	Abbreviation
1	Full Textual Description	Full Text
2	Abbreviated Textual Description	Abbreviated Txt
3	Capitalized Name	
4	Salt Name	
5	Alternate Name	

For more information about the Type Code, go to Chapter 2: Editorial Policies.

### **Transaction CD**

This is a 1-character field.

The Transaction CD indicates the file activity that last occurred for a record.

The current values are:

Value	Description
Α	Add
С	Change

Value	Description
D	Delete
b'	No Change

Note	All Transaction CDs are blank for Total Databases.	
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# **Description**

This is a 250-character field.

The Description field provides a textual description of the concept as defined by the Concept Type, Country Code, Concept ID, and Type Code.

#### Example:

Concept Type	Concept ID	Type Code	Description
1	26124	1	Zetia
Drug Name		Full Text Description	
1	26124	3	ZETIA
Drug Name		Capitalized Name	
2	26124	1	Thinlets GP Lancets (Does
Routed Drug		Full Text Description	not apply)
3	26124	1	Melatonin-Pyridoxine Oral
Routed Dose		Full Text Description	Tablet Extended Release
Form Drug			
4	26124	1	Chlorpheniramine-
Dispensable		Full Text Description	Phenylephrine Oral Syrup 1-
Drug			2.5 MG/5ML

### Reserve

This is a 67-character field.

The Reserve field is an unused field that may be used at a future date.

# **Route File**

#### (MF2RTE)

The Route File contains the fields associated with the route of administration. Specific route description data resides in the Description File (MF2DESC). The Route File includes additional historical concepts that are not reflected in the Drug Name File.

4-102 MED-File v2 Published: 11/11 Revised: 04/18 The Route File contains the following data elements:

Code	Data Element Name	Record Position	Type/Length	Picture
V001	Concept Type	1-5	N/5	9(5)
V006	Country Code	6-7	N/2	9(2)
V008	Concept ID	8-17	N/10	9(10)
V018	Transaction CD	18-18	C/1	X(1)
V019	Status	19-19	N/1	9(1)
V020	Link Value	20-29	N/10	9(10)
V030	Link Date	30-37	N/8	YYYYMMDD
V038	Reserve	38-48	C/11	X(11)

<b>Note</b> The shaded rows represent the unique key into the file.	
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### **Concept Type**

This is a 5-digit numeric field.

The Concept Type defines the type of concept that is represented by the Concept ID.

#### Valid Values:

Value	Description
00001	Drug Name
00002	Routed Drug
00003	Routed Dose Form Drug
00004	Dispensable Drug
00005	GPI
00006	GPPC5
00007	NDC-UPC-HRI
00008	Route
00009	Dose Form
00221	Dose Form Drug
00222	Strength-Strength UOM

Note	00008 (Route) is the only value used in this file.	
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# **Country Code**

This is a 2-digit numeric field.

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The Country Code represents the country to which a Route is specific.

Note 01 (USA) is the only value in use at this time.

# **Concept ID**

This is a 10-digit numeric field.

The Concept ID identifies the Route.

### **Transaction CD**

This is a 1-character field.

The Transaction CD indicates the file activity that last occurred for a record.

The current values are:

Value	Description
Α	Add
С	Change
D	Delete
b'	No Change

Note	All Transaction CDs are blank for Total Databases.	

### **Status**

This is a 1-character field.

The Status defines the current state of the Route concept.

#### Valid Values:

Value	Description	Abbreviation
1	Active Concept with Active Associated Products	Active w/Prod
2	Active w/Assc Prd Inactive <48 Months	Active w/Inact
3	Inactive w/Assc Prd Inactive >48 Months	Inactive w/Prd
4	Inactive w/no Assc. Products	Inac w/o Prd

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### **Link Value**

This is a 10-digit numeric field.

The Link Value identifies the new Concept ID that replaces the Concept ID in this record.

Note	The Link Value for this file is not in use at this time. For more information,
	go to Chapter 5, "Applications".

### **Link Date**

This is an 8-digit numeric field.

The Link Date represents the date the Concept ID was replaced by the Link Value.

Note	The Link Date for this file is not in use at this time. For more information,
	go to Chapter 5, "Applications".

#### Reserve

This is an 11-digit numeric field.

The Reserve field is an unused field that may be used at a future date.

# **Dose Form File**

#### (MF2FRM)

The Dose Form File contains the fields associated with the dosage form. Specific dosage form description data resides in the Description File (MF2DESC). The Dose Form File includes additional historical concepts that are not reflected in the Drug Name File.

The Dose Form File contains the following data elements:

Code	Data Element Name	Record Position	Type/Length	Picture
W001	Concept Type	1-5	N/5	9(5)
W006	Country Code	6-7	N/2	9(2)
W008	Concept ID	8-17	N/10	9(10)
W018	Transaction CD	18-18	C/1	X(1)

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Code	Data Element Name	Record Position	Type/Length	Picture
W019	Status	19-19	N/1	9(1)
W020	Link Value	20-29	N/10	9(10)
W030	Link Date	30-37	N/8	YYYYMMDD
W038	Reserve	38-48	C/11	X(11)

**Note** The shaded rows represent the unique key into the file.

# **Concept Type**

This is a 5-digit numeric field.

The Concept Type defines the type of concept that is represented by the Concept ID.

#### Valid Values:

Value	Description
00001	Drug Name
00002	Routed Drug
00003	Routed Dose Form Drug
00004	Dispensable Drug
00005	GPI
00006	GPPC5
00007	NDC-UPC-HRI
00008	Route
00009	Dose Form
00221	Dose Form Drug
00222	Strength-Strength UOM

**Note** 00009 (Dose Form) is the only value used in this file.

# **Country Code**

This is a 2-digit numeric field.

The Country Code represents the country to which a Dose Form is specific.

Note 01 (USA) is the only value in use at this time.

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### **Concept ID**

This is a 10-digit numeric field.

The Concept ID identifies the Dose Form.

### **Transaction CD**

This is a 1-character field.

The Transaction CD indicates the file activity that last occurred for a record.

The current values are:

Value	Description
Α	Add
С	Change
D	Delete
p,	No Change

Note All Transaction CDs are blank for Total Databases.
---

### **Status**

This is a 1-digit numeric field.

The Status defines the current state of the Dose Form concept.

#### Valid Values:

Value	Description	Abbreviation
1	Active Concept with Active Associated Products	Active w/Prod
2	Active w/Assc Prd Inactive <48 Months	Active w/Inact
3	Inactive w/Assc Prd Inactive >48 Months	Inactive w/Prd
4	Inactive w/no Assc. Products	Inac w/o Prd

### **Link Value**

This is a 10-digit numeric field.

The Link Value identifies the new Concept ID that replaces the Concept ID in this record.

Documentation Manual 4-107 Published: 11/11

Note	The Link Value for this file is not in use at this time. For more information,
	go to Chapter 5, "Applications".

### **Link Date**

This is an 8-digit numeric field.

The Link Date represents the date the Concept ID was replaced by the Link Value.

Note	The Link Date for this file is not in use at this time. For more information,
	go to Chapter 5, "Applications".

#### Reserve

This is an 11-character field.

The Reserve field is an unused field that may be used at a future date.

# Strength-Strength Unit of Measure File

#### (MF2STUOM)

The Strength-Strength Unit of Measure File contains the fields associated with a strength and strength unit-of-measure. The strength and strength unit-of-measure are included as individual attributes. A description of the Concept ID resides in the Description File (MF2DESC) and represents the combination of the strength and strength unit-of-measure. The Strength-Strength Unit of Measure File includes additional historical concepts that are not reflected in the Drug Name File.

The Strength-Strength Unit of Measure File contains the following data elements:

Code	Data Element Name	Record Position	Type/Length	Picture
X001	Concept Type	1-5	N/5	9(5)
X006	Country Code	6-7	N/2	9(2)
X008	Concept ID	8-17	N/10	9(10)
X018	Transaction CD	18-18	C/1	X(1)
X019	Strength	19-33	C/15	X(15)
X034	Strength Unit-of- Measure	34-48	C/15	X(15)

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Code	Data Element Name	Record Position	Type/Length	Picture
X049	Status	49-49	N/1	9(1)
X050	Link Value	50-59	N/10	9(10)
X060	Link Date	60-67	N/8	YYYYMMDD
X068	Reserve	68-96	C/29	X(29)

# **Concept Type**

This is a 5-digit numeric field.

The Concept Type defines the type of concept that is represented by the Concept ID.

#### Valid Values:

Value	Description
00001	Drug Name
00002	Routed Drug
00003	Routed Dose Form Drug
00004	Dispensable Drug
00005	GPI
00006	GPPC5
00007	NDC-UPC-HRI
00008	Route
00009	Dose Form
00221	Dose Form Drug
00222	Strength-Strength UOM

Note	00222 (Strength-Strength UOM) is the only value used in this file.
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# **Country Code**

This is a 2-digit numeric field.

The Country Code represents the country to which a Strength-Strength UOM is specific.

Note
------

### **Concept ID**

This is a 10-digit numeric field.

The Concept ID identifies the Strength-Strength Unit of Measure.

### **Transaction CD**

This is a 1-character field.

The Transaction CD indicates the file activity that last occurred for a record.

The current values are:

Value	Description
Α	Add
С	Change
D	Delete
b⁄	No Change

Note	All Transaction CDs are blank for Total Databases.

### Strength

This is a 15-character field.

The Strength is a character representation of the product's ingredient strength. When combined with the Strength Unit of Measure, it represents the dosage strength as provided by the manufacturer.

## **Strength Unit-Of-Measure**

This is a 15-character field.

The Strength Unit Of Measure, when combined with the Strength, represents the dosage strength as provided by the manufacturer.

#### **Status**

This is a 1-digit numeric field.

The Status defines the current state of the Strength-Strength UOM concept.

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#### Valid Values:

Value	Description	Abbreviation
1	Active Concept with Active Associated Products	Active w/Prod
2	Active w/Assc Prd Inactive <48 Months	Active w/Inact
3	Inactive w/Assc Prd Inactive >48 Months	Inactive w/Prd
4	Inactive w/no Assc. Products	Inac w/o Prd

### **Link Value**

This is a 10-digit numeric field.

The Link Value identifies the new Concept ID that replaces the Concept ID in this record.

Note	The Link Value for this file is not in use at this time. For more information,
	go to Chapter 5, "Applications".

### **Link Date**

This is an 8-digit numeric field.

The Link Date represents the date the Concept ID was replaced by the Link Value.

Note	The Link Date for this file is not in use at this time. For more information,
	go to Chapter 5, "Applications".

#### Reserve

This is a 29-character field.

The Reserve field is an unused field that may be used at a future date.

# **Drug Concept ID to Ingredient Set ID File**

#### (MF2SET)

The Drug Concept ID to Ingredient Set ID File associates ingredients to both the Dispensable Drug and to the NDC-UPC-HRI. The Drug Concept ID to Ingredient Set ID File includes additional historical concepts that are not reflected in the Drug Name File.

Note	The Dispensable Drug and the Drug Descriptor are one and the same. The terms may be used interchangeably in this and other Wolters Kluwer Clinical Drug Information documents.		
Note	In the absence of ingredient information, or when there is conflicting ingredient information, the Ingredient Set ID will be "0000000000".		

The Drug Concept ID to Ingredient Set ID File contains the following data elements:

Code	Data Element Name	Record Position	Type/Length	Picture
Y001	Concept Type	1-5	N/5	9(5)
Y006	Country Code	6-7	N/2	9(2)
Y008	Concept ID	8-27	C/20	X(20)
Y028	Ingredient Set ID	28-37	N/10	9(10)
Y038	Transaction CD	38-38	C/1	Х
Y039	Representative Set Indicator	39-39	C/1	Х
Y040	Reserve	40-64	C/25	X(25)

# **Concept Type**

This is a 5-digit numeric field.

The Concept Type defines the type of concept that is represented by the Concept  $\ensuremath{\mathsf{ID}}.$ 

### Valid Values:

Value	Description
00001	Drug Name
00002	Routed Drug
00003	Routed Dose Form Drug
00004	Dispensable Drug
00005	GPI
00006	GPPC5
00007	NDC-UPC-HRI
00008	Route
00009	Dose Form

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Value	Description
00221	Dose Form Drug
00222	Strength-Strength UOM

Note	00004 (Dispensable Drug), and 00007 (NDC-UPC-HRI) are the only values
	used in this file.

# **Country Code**

This is a 2-digit numeric field.

The Country Code represents the country to which a drug concept is specific.

Note	01 (USA) is the only value in use at this time.
------	---

# **Concept ID**

This is a 20-character field.

The Concept ID identifies the drug concept, either a Dispensable Drug or a NDC-UPC-HRI. A description of the Dispensable Drug value is available in the Description File (MF2DESC).

# Ingredient Set ID

This is a 10-digit numeric field.

The Ingredient Set ID represents the collection of active and significant inactive ingredients of a product formulation.

In the absence of ingredient information, or when there is conflicting ingredient information, the Ingredient Set ID will be "0000000000".		
For outsourcing facility products, the ingredient set ID represents only the inactive ingredients for a product formulation. Significant inactive ingredients are excluded for these products.		

### **Transaction CD**

This is a 1-character field.

The Transaction CD indicates the file activity that last occurred for a record.

The current values are:

Value	Description
Α	Add
С	Change
D	Delete
p,	No Change

Note All Transaction CDs are blank for Total Databases.	
---	--

### **Representative Set Indicator**

This is a 1-character field.

The Representative Set Indicator designates whether the Concept ID has a unique Ingredient Set ID or if a representative Ingredient Set ID is assigned.

#### Valid Values:

Value	Description	Definition	
0	Unassigned	Multiple Ingredient Set IDs exist and no Ingredient Set ID is assigned	
1	Exact Match Set	One Ingredient Set ID exists	
1			
2	Representative Set	Multiple Ingredient Set IDs exist and one Ingredient Set ID is assigned	
3	Set Cannot be Assigned	Multiple ingredient sets exist and an ingredient set will not be assigned.	

#### Reserve

This is a 25-character field.

The Reserve field is an unused field that may be used at a future date.

# Ingredient Set ID to Ingredient ID File

### (MF2INGS)

The Ingredient Set ID to Ingredient ID File contains the individual Ingredient IDs that are associated to the Ingredient Set ID. In addition, this file has a flag that designates each Ingredient Identifier as either an active or inactive ingredient.

4-114 MED-File v2 Published: 11/11 Revised: 04/18 The Ingredient Set ID to Ingredient ID File contains the following data elements:

Code	Data Element Name	Record Position	Type/Length	Picture
Z001	Ingredient Set ID	1-10	N/10	9(10)
Z011	Ingredient Identifier	11-20	N/10	9(10)
Z021	Active/Inactive Ingredient Flag	21-21	C/1	Х
Z022	Transaction CD	22-22	C/1	Χ
Z023	Reserve	23-32	C/10	X(10)

<b>Note</b> The shaded rows represent the unique key into the file.
---

# **Ingredient Set ID**

This is a 10-digit numeric field.

The Ingredient Set ID represents the collection of active and significant inactive ingredients of a product formulation.

Note	For outsourcing facility products, the ingredient set ID represents only the
	inactive ingredients for a product formulation. Significant inactive
	ingredients are excluded for these products.

# **Ingredient Identifier**

This is a 10-digit numeric field.

The Ingredient Identifier represents a unique combination of Ingredient Drug ID, Ingredient Strength Value, and Ingredient Strength UOM (Combined).

### Example:

Ingredient Set ID	Ingredient ID	Drug ID/ Ingredient Drug Name	Ingredient Strength	Ingredient Strength Unit of Measure (Combined)
19588	30738	4004 ATORVASTATIN CALCIUM	10	MG

Ingredient Set ID	Ingredient ID	Drug ID/ Ingredient Drug Name	Ingredient Strength	Ingredient Strength Unit of Measure (Combined)
43580	16722	2024 AMLODIPINE BESYLATE	5	MG
	30738	4004 ATORVASTATIN CALCIUM	10	MG

## **Active/Inactive Ingredient Flag**

This is a 1-character field.

The Active/Inactive Ingredient Flag is a one-character flag that indicates whether the ingredient is an active ingredient or an inactive ingredient.

#### Valid Values:

ID	Description
A	Active Ingredient
I	Inactive Ingredient

Note Only those ingredients that are considered clinically significant are		
	generally included. For example, alcohol and Tartrazine. Other inactive	
	ingredient information is generally not included. A list of significant inactive	
	ingredients is available upon request.	

Note In compounded products from outsourcing facilities, only active ingredients are included. All inactive ingredients will be excluded. Users of products manufactured by outsourcing facilities should understand that comprehensive allergy screening and alerting for allergenic inactive ingredients will NOT occur. Products from outsourcing facilities may be identified using the limited distribution code of 03.

### **Transaction CD**

This is a 1-character field.

The Transaction CD indicates the file activity that last occurred for a record.

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#### The current values are:

Value	Description
Α	Add
С	Change
D	Delete
b⁄	No Change

### Reserve

This is a 10-character field.

The Reserve field is an unused field that may be used at a future date.

# Ingredient ID to Drug-Strength File

#### (MF2STR)

The Ingredient ID to Drug-Strength File contains the strengths and strength unit of measure of each Ingredient Identifier. In addition, this file contains the strength unit of measure field in both combined and individual components so that volume unit of measures can be represented.

The Ingredient ID to Drug-Strength File contains the following data elements:.

Code	Data Element Name	Record Position	Type/Length	Picture
1001	Ingredient Identifier	1-10	N/10	9(10)
1011	Reserve-1	11-12	C/2	X(2)
1013	Transaction CD	13-13	C/1	Х
1014	Ingredient Drug ID	14-23	N/10	9(10)
1024	Ingredient Strength Value	24-36	N/13	9(8)V9(5)
1037	Ingredient Strength UOM (combined)	37-47	C/11	X(11)
1048	Ingredient Strength UOM (individual)	48-58	C/11	X(11)
1059	Volume Value	59-71	N/13	9(8)V9(5)
1072	Volume Unit of Measure	72-82	C/11	X(11)
1083	Reserve-2	83-112	C/30	X(30)

Published: 11/11 Revised: 04/18 Note

The shaded row represents the unique key into the file.

### Ingredient Identifier

This is a 10-digit numeric field.

The Ingredient Identifier represents a unique combination of Ingredient Drug ID, Ingredient Strength Value, and Ingredient Strength UOM (Combined).

#### Reserve-1

This is a 2-character field.

The Reserve-1 field is an unused field that may be used at a future date.

### **Transaction CD**

This is a 1-character field.

The Transaction CD indicates the file activity that last occurred for a record.

The current values are:

Value	Description
Α	Add
С	Change
D	Delete
b⁄	No Change

**Note** All Transaction CDs are blank for Total Databases.

# **Ingredient Drug ID**

This is a 10-digit numeric field.

The Ingredient Drug ID represents a unique ingredient description. It is systemgenerated and contains no logic.

# **Ingredient Strength Value**

This is a 13-digit numeric field.

4-118 MED-File v2 Published: 11/11 Revised: 04/18 The Ingredient Strength Value is a numeric value representing the metric strength for a product, where available. In addition, this value may sometimes indicate a ratio strength or percentage.

## Ingredient Strength UOM (combined)

This is an 11-character field.

The Ingredient Strength UOM (combined) is a combined character representation describing the units of the Ingredient Strength Value. It may be a percentage, or part of a ratio strength. The combined value will include volume units, if applicable, with slashes (for example, MG/5ML).

## Ingredient Strength UOM (individual)

This is an 11-character field.

The Ingredient Strength Unit of Measure (individual) is an individual character representation describing the units of the Ingredient Strength Value. It may be a percentage, or part of a ratio strength.

Note The Ingredient Strength UOM (individual) is not in use at this time.

#### **Volume Value**

This is a 13-digit numeric field.

The Volume Value is a numeric value representing the volume used in the Ingredient Strength Unit of Measure (combined), when applicable.

**Note** The Volume Value is not in use at this time.

#### **Volume Unit of Measure**

This is an 11-character field.

The Volume Unit of Measure is an individual character representation describing the volume represented in the Ingredient Strength Value, when applicable.

**Note** The Volume Unit of Measure is not in use at this time.

#### Reserve-2

This is a 30-character field.

The Reserve-2 field is an unused field that may be used at a future date.

# **Ingredient Drug File**

#### (MF2IDRG)

The Ingredient Drug File is a dictionary of generic ingredients with association to common identifiers for the ingredients.

The Ingredient Drug File contains the following data elements:

Code	Data Element Name	Record Position	Type/Length	Picture
2001	Ingredient Drug ID	1-10	N/10	9(10)
2011	Transaction CD	11-11	C/1	Х
2012	CAS Number	12-31	C/20	X(20)
2032	Knowledge Base Code 7	32-38	N/7	9(7)
2039	Reserve-1	39-41	C/3	X(3)
2042	Ingredient Drug Name	42-101	C/60	X(60)
2102	Generic ID	102-111	C/10	X(10)
2112	Reserve-2	112-128	C/17	X(17)

The shaded row represents the unique key into the file. Note

# **Ingredient Drug ID**

This is a 10-digit numeric field.

The Ingredient Drug ID represents a unique ingredient. It is system-generated and contains no logic.

### **Transaction CD**

This is a 1-character field.

The Transaction CD indicates the file activity that last occurred for a record.

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#### The current values are:

Value	Description
Α	Add
С	Change
D	Delete
b/	No Change

### **CAS Number**

This is a 20-character field.

When available, the Chemical Abstracts Service (CAS) Registry Numbers are unique identifiers for chemical substances. A CAS Registry Number itself has no inherent chemical significance, but it does provide an unambiguous way to identify a chemical substance or molecular structure when there are many possible systematic, generic, or proprietary names available.

### **Knowledge Base Code 7**

This is a 7-digit numeric field.

The Knowledge Base Drug Code 7 (KDC-7) is a code that Wolters Kluwer Clinical Drug Information uses that defines ingredients. For an Ingredient Drug ID that does not have a KDC-7, this field will be zero-filled.

Note	The KDC is not a hierarchical value and does not correlate to the GPI in any
	way.

#### Reserve-1

This is a 3-character field.

The Reserve-1 field is an unused field that may be used at a future date.

# **Ingredient Drug Name**

This is a 60-character field.

The Ingredient Drug Name field is an upper-case ingredient name.

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#### **Generic ID**

This is a 10-character field.

The Generic ID field is a proprietary Wolters Kluwer Clinical Drug Information value for a specific generic ingredient.

#### Reserve-2

This is a 26-character field.

The Reserve-2 field is an unused field that may be used at a future date.

# **Secondary Alternate ID File**

### (MF2SEC)

The Secondary Alternate ID File contains the secondary and any alternate marketplace IDs for a packaged drug.

For example, a drug may have an NDC, but may also have a UPC. This file links the IDs together.

Currently, alternate IDs are either NDCs, UPCs, or HRIs. Additional ID types may be used in the future.

The Secondary Alternate ID File contains the following data elements:

Code	Data Element Name	Record Position	Type/Length	Picture
3001	External Drug ID (NDC- UPC-HRI)	1-20	C/20	X(20)
3021	External Drug ID Format Code	21-21	C/1	X
3022	Alternate Drug ID	22-41	C/20	X(20)
3042	Alternate Drug ID Format Code	42-42	C/1	Х
3043	Transaction CD	43-43	C/1	Х
3044	Reserve	44-64	C/21	X(21)

**Note** The shaded rows represent the unique key into the file.

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### **External Drug ID (NDC-UPC-HRI)**

This is a 20-character field.

NDCs, UPCs, and HRIs are 10-character codes used to identify drug products. Surgical supplies and non-prescription drug products may have an NDC and an HRI or UPC according to the standards set forth by the Uniform Product Code Council, Inc. These codes are converted to eleven characters according to NCPDP standards.

**Note** The External Drug ID and the Alternate Drug ID may be the same value with different format codes.

## **External Drug ID Format Code**

This is a 1-character field.

The External Drug ID Format Code identifies the format of the NDC-UPC-HRI. Use the External Drug ID Format Code with an NDC, UPC, or HRI to determine the following:

- where to place dashes when formatting for display
- how to convert from the 10- to 11-character format
- how to convert from the 11- to 10-character format

#### Valid Values:

Code	Represents	ID Type
1	4-4-2	NDC
2	5-3-2	NDC
3	5-4-1	NDC
4	4-6	HRI
5	5-5	UPC
6	5-4-2	NDC

The codes convert as follows:

NDC		NCPDP Standard 11- character NDC	11-character NDC (with hyphens)	ID Format Code
4-4-2 (9999-9999-99)		5-4-2 (09999999999)	09999-9999-99	1
5-3-2 (99999-999-99)		5-4-2 (99999099999)	99999-0999-99	2
5-4-1 (99999-9999-9)	Converts	5-4-2 (99999999999)	99999-9999-09	3
5-4-2 (99999-9999-99	То	5-4-2 (99999999999)	99999-9999-99	6
4-6 (9999-999999)		5-6 (09999999999)	9999-999999	4
5-5 (99999-99999)		5-6 (99999099999)	99999-99999	5

### **Alternate Drug ID**

This is a 20-character field.

NDCs, UPCs, and HRIs are 10-character codes used to identify drug products. Surgical supplies and non-prescription drug products may have an NDC and an HRI or UPC according to the standards set forth by the Uniform Product Code Council, Inc. These codes are converted to eleven characters according to NCPDP standards.

**Note** The External Drug ID and the Alternate Drug ID may be the same value with different format codes.

# **Alternate Drug ID Format Code**

This is a 1-character field.

The Alternate Drug ID Format Code identifies the format of the NDC-UPC-HRI [Data Element Code 6001]. Use the Alternate Drug ID Format Code with an NDC, UPC, or HRI to determine:

- where to place dashes when formatting for display
- how to convert from the 10 to 11-character format
- how to convert from the 11 to 10-character format

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### Valid Values:

Code	Represents	ID Type
1	4-4-2	NDC
2	5-3-2	NDC
3	5-4-1	NDC
4	4-6	HRI
5	5-5	UPC
6	5-4-2	NDC

The codes convert as follows:

NDC		NCPDP Standard 11-character NDC	11-character NDC (with hyphens)	ID Type Code	ID Format Code
4-4-2 (9999-9999-99)		5-4-2 (09999999999)	09999-9999-99	1	1
5-3-2 (99999-999-99)		5-4-2 (99999099999)	99999-0999-99	1	2
5-4-1 (99999-9999-9)	rts to	5-4-2 (9999999999)	99999-9999-09	1	3
5-4-2 (99999-9999-99	Convert	5-4-2 (9999999999)	99999-9999-99	1	6
4-6 (9999-999999)		5-6 (0999999999)	9999-999999	2	4
5-5 (99999-99999)		5-6 (99999099999)	99999-99999	2 or 3	5

### **Transaction CD**

This is a 1-character field.

The Transaction CD indicates the file activity that last occurred for a record.

The current values are:

Value	Description
Α	Add
С	Change
D	Delete
p,	No Change

Note All Transaction CDs are blank for Total Databases.

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### Reserve

This is a 21-character field.

The Reserve field is an unused field that may be used at a future date.

## **Reference Name File**

### (MF2RNM)

The Reference Name File associates a Concept ID to its generically-named Concept ID. Concept IDs for brands can have a Medi-Span Reference Flag to indicate that the brand concept can be used to construct a generic name with a brand name reference. For example, Ibuprofen Oral Tablet 400 MG (Motrin).

The Reference Name File contains the following data elements:

Code	Data Element Name	Record Position	Type/Length	Picture
4001	Concept Type	1-5	N/5	9(5)
4006	Country Code	6-7	N/2	9(2)
4008	Concept ID	8-17	N/10	9(10)
4018	ID for Generic Named Drug	18-27	N/10	9(10)
4028	Transaction CD	28-28	C/1	Х
4029	Medi-Span Reference Flag	29-29	C/1	Х
4030	Reserve	30-48	C/19	X(19)

Note The shaded rows represent the unique key into the file.	
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## **Concept Type**

This is a 5-digit numeric field.

The Concept Type defines the type of concept that is represented by the Concept ID.

#### Valid Values:

Value	Description
00001	Drug Name
00002	Routed Drug
00003	Routed Dose Form Drug

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Value	Description
00004	Dispensable Drug
00005	GPI
00006	GPPC5
00007	NDC-UPC-HRI
80000	Route
00009	Dose Form
00221	Dose Form Drug
00222	Strength-Strength UOM

Note

00001 (Drug Name), 00002 (Routed Drug), and 00004 (Dispensable Drug) are the only values used in this file.

### **Country Code**

This is a 2-digit numeric field.

The Country Code represents the country to which a drug concept is specific.

Note

01 (USA) is the only value in use at this time.

## **Concept ID**

This is a 10-digit numeric field.

The Concept ID identifies a Drug Name, Routed Drug, or Dispensable Drug.

The Dispensable Drug and the Drug Descriptor are the same. The terms may be used interchangeably in this and other Wolters Kluwer Clinical Drug Information documents.

### Note

The Drug Names, Routed Drugs, and Dispensable Drugs represented in this file reflect those available in the Drug Name File through their association to the DDIDs in the Drug Name File. The SDI Name File, Routed Drug File, and Dispensable Drug File include records that are not included here.

# **ID for Generic Named Drug**

This is a 10-digit numeric field.

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The ID for Generic Named Drug is a Concept ID representing a generically-named Drug Name, Routed Drug, or Dispensable Drug.

### **Transaction CD**

This is a 1-character field.

The Transaction CD indicates the file activity that last occurred for a record.

The current values are:

Value	Description
Α	Add
С	Change
D	Delete
b⁄	No Change

Note	All Transaction CDs are blank for Total Databases.	
------	--	--

### **Medi-Span Reference Flag**

This is a 1-character field.

The Medi-Span Reference Flag is assigned by Wolters Kluwer Clinical Drug Information to identify a reference brand name drug for the records that have the same 14-character GPI value. There may be zero, one, or many brand names designated as reference brand name drugs even though they share the same 14-character GPI.

Note	Drugs assigned to partial GPIs are not designated as reference brand name
	drugs.

#### Valid Values:

Value	Description
N	Is not a reference brand name
Υ	Is a reference brand name

### Reserve

This is a 19-character field.

4-128 MED-File v2 Published: 11/11 Revised: 04/18 The Reserve field is an unused field that may be used at a future date.

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# **Chapter 5: Applications**

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### Introduction

This chapter highlights some of the many algorithms and recommendations for deploying MED-File v2 in your end-user applications. The many and varied functions performed by the user will likely determine what and how certain data is deployed, what data you store in a database or patient record, and what is made available to users in the form of applications and reporting. In some

instances, the presentation of information to the user is critical to patient safety and is addressed in the chapter, as applicable.

Note	The terms Drug Descriptor Identifier and Dispensable Drug Identifier, also known as the DDID are used interchangeably in this and other documentation. In some files, the ID is a six digit number. In other files, the DDID is a 10 digit number. The significant digits of the number are the same.
Note	Examples in this chapter are for illustrative purposes only and may not reflect current data.

# **Storing Terminology**

A critical step in deploying MED-File v2 in your applications is establishing processes to store and maintain terminology. This is especially important when storing information in the patient profile/electronic medical record. However, it is also applicable to other applications, even if the operations are not directly related to patient care.

When the following terminologies are stored, the description should be stored in addition to the code/value/identifier that represents it:

- Dispensable Drug ID (DDID)
- Other name-based drug concepts such as the Drug Name, Routed Drug, Routed Dose Form Drug, and Dose Form Drug
- Generic Product Identifier (GPI)
- Ingredients

Some of Wolters Kluwer Clinical Drug Information clinical screening applications utilize the Knowledge Base Drug Code (KDC). Therefore, storing this value is also recommended.

In some cases, the NDC-UPC-HRI is necessary to uniquely identify the specific drug product that was dispensed and/or administered to the patient.

With proper storage and maintenance of these terminologies:

- the severity or impact of error corrections by Wolters Kluwer Clinical Drug Information can be quickly identified and reviewed on a patient-bypatient/time-of-therapy basis.
- removal of a drug product from the Drug Name File when a name is no longer associated with the drug product currently on the market, will not

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cause a patient profile to become unusable due to an unidentifiable drug. The drug's generic name or product name will be available in the patient profile for historical reference.

- an additional safety feature can be implemented when reviewing a
  patient profile by comparing the description generated by the stored
  value with the stored drug description. If the two descriptions are not
  the same, the reviewer can determine if an error exists.
- inclusion of the GPI and KDC allows for simplified access to these values for clinical screening and for further review of these values during updating.

# **Maintaining Terminology**

### Changes to the DDID

Changes to the DDID can occur at any time. It is important to monitor these changes and manage them in your database and in patient records. Refer to Associating New and Old Dispensable Drugs (DDIDs) later in this chapter.

In addition, error corrections to the DDID are reflected in the Error Correct File. The file will alert you to DDID corrections so you can determine any terminology maintenance that needs to be made. Refer to Processing Error Corrections later in this chapter.

# **Processing old DDIDs**

DDIDs will remain in the Drug Name file for up to 48 months after all associated drug products linked to that DDID have been inactive. However, DDIDs are not removed from the Dispensable Drug File after that 48 month period. In the event that you need to process records using older DDIDs, use the Dispensable Drug File.

# Changes to the GPI

GPI changes are one of two types. Each type requires you to carefully assess the impact of these changes to your database and to patient records.

Error corrections are made at any time. MED-File v2 does not provide a new to old link. However, the changes are published by Wolters Kluwer Clinical Drug Information when they occur. Contact Wolters Kluwer Clinical Drug Information if you wish to subscribe to this publication.

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Wolters Kluwer Clinical Drug Information also performs "planned" GPI changes, usually on a semi-annual basis in April and October. The list of planned changes is published one quarter in advance and made available to all MED-File v2 customers. This list identifies the changes in GPI assignment for drugs.

### **Changes to NDC-UPC-HRIs**

Changes to NDC-UPC-HRIs can occur at any time. Refer to Associating New and Old NDC-UPC-HRIs later in this chapter.

In addition, error corrections associated with attributes of the NDC are reflected in the Error Correct File. This file will alert you to the corrections so you can determine the impact to your applications.

# **Processing Error Corrections**

The Error Correct File enables you to identify certain types of corrections that Wolters Kluwer Clinical Drug Information has made to the data. The error correction itself appears in the appropriate data file within MED-File v2. The purpose of the Error Correct File is to "flag" the corrections. The needs of your end-users will determine the impact of the correction and any actions that you or they may take within the application. For example, the manufacturer's correction of a drug price may or may not be significant to the end-user's business operations.

The following types of error corrections are provided in the Error Correct File:

- Drug Descriptor Identifier (aka Dispensable Drug)
- NDC-UPC-HRI
- NDC-UPC-HRI and Price Type

**Note** Wolters Kluwer Clinical Drug Information recommends that all error corrections be reviewed before they are processed.

The Error Correct File is provided as part of the Incremental Update. It is not provided with a Total Replacement.

The following example illustrates how to use the Error Correct File to identify the associated record in your database.

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### Example:

Key Identifier	Unique Key	Data Element Code	Data Element Length
2	12345678901	H023	008

- Key Identifier of 2 = NDC-UPC-HRI
- Unique Key = the specific NDC-UPC-HRI
- Date Element Code H023 = Generic Product Packaging Code (GPPC)
- Data Element Length = the length of the Generic Product Packaging Code field

This record in the Error Correct File indicates that a correction has been made to the GPPC assignment for an NDC-UPC-HRI in the NDC File. The presence of this record enables you to evaluate the impact of the change by reviewing the GPPC assignment for the NDC-UPC-HIR currently in your database before applying your Incremental Update to deploy the corrected value.

# **Maintaining Price History**

### **Updating The Price History File**

MED-File v2 provides, at most, one current price for each price type supported in the product. The NDC Price File includes AWP, DP, WAC, and CMS FUL pricing information as individual records. The GPPC Price File includes AAWP and GEAP pricing information. An Effective Date is associated with each individual pricing record.

If you receive Incremental Updates, a Transaction Code is provided for each added, changed, or deleted record within that particular Incremental Update. The Transaction Code will reflect only the most recent price change during the update cycle. For example, if you receive weekly updates and the price changed multiple times from one weekly update to another, the Incremental Update that you receive will only reflect the current price at the time of the update.

**Note** If you receive a Total Replacement, the Transaction Code will be blank.

Use the Transaction Codes as follows to maintain a price history file and to update end-user applications with the current price.

- If the Transaction Code is A (add), add the current price to you price history file.
- If the Transaction Code is C (change)

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- > If the primary key matches a record in your current file, replace the current information in your file with the new information.
- > If the primary key does not match a record in your current file, add the record to your file.
- If the Transaction Code is D (delete) you may decide whether or not to delete pricing history for that record, depending on your needs and the needs of your end-users.

The Error Correct File can be used along with the NDC Price File to manage the processing of pricing records.

The example below illustrates a chronological sequence of price history maintenance.

### Sample 1

# Sample January 1, 2012 Initial Load for AWP price for NDC-UPC-HRI 12345678901

NDC-UPC-HRI	Price Type	Effective Date	Unit Price	Transaction Code
12345678901	3	20111228	00000009966	Α

### Resulting Local Price History File

NDC-UPC-HRI	Price Type	Effective Date	Unit Price
12345678901	3	20111228	0000009966

# Sample February 1, 2012 Incremental Update for AWP price for NDC-UPC-HRI 12345678901

NDC-UPC-HRI	Price Type	Effective Date	Unit Price	Transaction Code
12345678901	3	20120123	0000010097	С

### Resulting Local Price History File

NDC-UPC-HRI	Price Type	Effective Date	Unit Price
12345678901	3	20111228	0000009966
12345678901	3	20120123	0000010097

Sample March 1, 2012 Incremental Update for AWP price for NDC-UPC-HRI 12345678901

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Note	For the purposes of this example, a corresponding record would also appear
	in the Error Correct File.

NDC-UPC-HRI	Price Type	Effective Date	Unit Price	Transaction Code
12345678901	3	20120123	0000010077	С

### Resulting Local Price History File

NDC-UPC-HRI	Price Type	Effective Date	Unit Price
12345678901	3	20111228	0000009966
12345678901	3	20120123	0000010077

# Sample April 1, 2012 Incremental Update for AWP price for NDC 12345678901

NDC-UPC-HRI	Price Type	Effective Date	Unit Price	Transaction Code
12345678901	3	20120315	00000010080	С

### Resulting Local Price History File

NDC-UPC-HRI	Price Type	Effective Date	Unit Price
12345678901	3	20112228	0000009966
12345678901	3	20120123	0000010077
12345678901	3	20120315	00000010080

# **Displaying Drugs and Creating Drug Selection Lists**

There are several options for displaying drugs in end-user applications. The needs of the user will define the type of drug concept that is used and its ultimate formatting.

The Dispensable Drug description can be created using data elements from the Drug Name File as follows:

- Drug Name
- Route of Administration Code
- Dosage Form
- Strength
- Strength Unit-of-Measure

#### Note

The two-character Route of Administration Code and four-character Dosage Form are not to be displayed or provided in print form in end-users applications. The values should be translated to their corresponding Value Descriptions as defined in the Validation/Translation File. Significant patient safety issues are associated with the use of non-standard abbreviations such as those found in these data fields.

The fields can be displayed in order of their appearance in the Drug Name File, or they can be reordered or removed, depending on the needs of the end-user.

The Description File also provides the Dispensable Drug, as well as additional descriptions for more generalized name-based concepts. In addition to the Dispensable Drugs in the Drug Name File, the Description File provides concepts for those drugs that have been inactive for more than 48 months. When displaying drugs, especially in selection lists (also referred to as picklists), the Status field on the associated Concept ID enables you to exclude items that are no longer associated to active drug products, if appropriate for your application. For example, the Status for a Dispensable Drug is found in the Dispensable Drug File, while the Status for a Routed Dose Form Drug is found in the Routed Drug Form File.

The descriptions in the Description File exist as text strings. The Country Code is 01 USA. For the purposes of these examples, the Type Code is 1 - Full Textual Description. For example:

Concept Type & Description	Example
00001 Drug Name	Lipitor
00002 Routed Drug	Lipitor Oral
00003 Routed Dose Form Drug	Lipitor Oral Tablet
00221 Dose Form Drug	Lipitor Tablet
00004 Dispensable Drug	Lipitor Oral Tablet 10 MG

Information is provided later in this chapter, enabling you to:

- Associate brand and generic drug names
- Construct alternate drug names, dose forms, and strength/strength unit of measure

The Dispensable Drug File includes the Name Source field. This field can be used to identify those generic name based Dispensable Drug values and descriptions that have been created for which no marketed drug product exists. This occurs when a newly marketed, patented drug is marketed but no generic drug

products are available. You may elect to exclude those items from a picklist or otherwise identify them for the end-user.

### For example:

Dispensable Drug Concept ID	Description	Name Source	Definition
0000080693	Rosuvastatin Calcium Oral Tablet 10 MG	0	Generic name; no products marketed with this name
0000083314	Crestor Oral Tablet 10 MG	1	Product name; products are marketed with this name
0000030825	Simvastatin Oral Tablet 10 MG	2	Generic name; products also marketed with this name

Similarly, the Drug Name File includes the Name Source Code.

### For example:

Drug Descriptor Identifier	Description	Name Source	Definition
080693	Rosuvastatin Calcium Oral Tablet 10 MG	G	No marketed products with this name
083314	Crestor Oral Tablet 10 MG	Р	Products are marketed with this name
030825	Simvastatin Oral Tablet 10 MG	Р	Products are marketed with this name

If you are working with Surescripts on quality electronic prescribing guidelines and would like information about working with Wolters Kluwer Clinical Drug Information drug names, contact Wolters Kluwer Clinical Drug Information for additional information.

# **Enabling Name-based Searching**

If your applications will enable end-users to search for drugs by name, Wolters Kluwer Clinical Drug Information recommends that searching be done anywhere in the string (such as "contains") and not by names that "begin with". The order of ingredients in drug name may vary; therefore, the user should be presented

with the full complement of results. For example, a search based on "begins with Simvastatin" would not identify the drug name "Ezetimibe-Simvastatin" that would be found in a "contains Simvastatin" search.

# Retrieving Routed Drug(s) for a Drug Name

Follow the steps below to retrieve the Routed Drug(s) associated with a Drug Name.

 Using the Drug Name and its associated Type Code, retrieve the Concept ID from the Description File. The Concept Type for a Drug Name is 00001. The Country Code is 01 USA.

### Example:

Using the Drug Name of "Imitrex", Type Code of "1", Concept Type of "00001", and Country Code of "01", the following would be retrieved:

Concept Type	Country Code	Concept ID	Type Code	Description
00001	01	0000005749	1	Imitrex

2. The Concept ID in the Description File represents a Drug Name. It is treated as the Drug Name ID in the Routed Drug File. Using the Concept ID from Step 1 as the Drug Name ID, retrieve all corresponding records in the Routed Drug File. The Concept Type for a Routed Drug is 00002. The Country Code is 01 USA.

#### Example:

Using the Drug Name ID of "0000005749", Concept Type of "00002", and Country Code of "01" the following would be retrieved:

Concept Type	Country Code	Concept ID	Drug Name ID	Route ID	Status
00002	01	0000005839	0000005749	00022	1
00002	01	0000006651	0000005749	00009	4
00002	01	0000013643	0000005749	00024	1
00002	01	0000025763	0000005749	00028	1

3. For each record obtained in Step 2, use the Concept ID and desired Type Code to retrieve the associated Description for the Routed Drug from the

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Description File. The Concept Type for a Routed Drug is 00002. The Country Code is 01 USA.

### Example:

Using the Concept IDs of "0000005839", "0000006651", "0000013643", and "0000025763", Concept Type of "00002", Country Code of "01", and Type Code of "1", the following would be retrieved:

Concept Type	Country Code	Concept ID	Type Code	Description
00002	01	0000005839	1	Imitrex Oral
00002	01	0000006651	1	Imitrex Injection
00002	01	0000013643	1	Imitrex Oral
00002	01	0000025763	1	Imitrex Subcutaneous

# Retrieving Routed Dose Form Drug(s) for a Drug Name

Follow the steps below to retrieve the Routed Dose Form Drug(s) associated with a Drug Name.

1. Using the Drug Name and its associated Type Code, retrieve the Concept ID from the Description File. The Concept Type for a Drug Name is 00001. The Country Code is 01 USA.

### Example:

Using the Drug Name of "Imitrex", Type Code of "1", Concept Type of "00001", and Country Code of "01", the following would be retrieved:

Concept Type	Country Code	Concept ID	Type Code	Description
00001	01	0000005749	1	Imitrex

2. The Concept ID in the Description File represents a Drug Name. It is treated as the Drug Name ID in the Routed Drug File. Using the Concept ID from Step 1 as the Drug Name ID, retrieve all corresponding records in the Routed Drug File. The Concept Type for a Routed Drug is 00002. The Country Code is 01 USA.

Using the Drug Name ID of "0000005749", Concept Type of "00002", and Country Code of "01" the following would be retrieved:

Concept Type	Country Code	Concept ID	Drug Name ID	Route ID	Status
00002	01	0000005839	0000005749	00022	1
00002	01	0000006651	0000005749	00009	4
00002	01	0000013643	0000005749	00024	1
00002	01	0000025763	0000005749	00028	1

3. The Concept ID in the Routed Drug File represents a Routed Drug. Therefore, it is treated as the Routed Drug ID in the Routed Drug Form File. Using the Concept ID from Step 2 as the Routed Drug ID, retrieve all corresponding records in the Routed Drug Form File. The Concept Type for a Routed Dose Form Drug is 00003. The Country Code is 01 USA.

### Example:

Using the Routed Drug IDs of "0000005839", "0000006651", "0000013643", and "0000025763", Concept Type of "00003", and Country Code of "01", the following would be retrieved:

Concept Type	Country Code	Concept ID	Routed Drug ID	Dose Form ID*	Status
00003	01	000007600	0000005839	00070	1
00003	01	0000008607	0000006651	00070	1
00003	01	0000017400	0000013643	00081	1
00003	01	0000030591	0000025763	00043	3
00003	01	0000030592	0000025763	00070	1

<sup>\*</sup> The Dose Form ID is not the same value as the Dosage Form in the Drug Name File. Refer to Associating Dosage Form in the Drug Name File to Dose Form in the Description File for information.

4. For each record obtained in Step 3, use the Concept ID and desired Type Code to retrieve the associated Description in the Description File. The Concept Type for a Routed Dose Form Drug is 00003. The Country Code is 01 USA.

Using the Concept IDs of "0000007600", "0000008607", "0000017407", "0000030591", and "0000030592", Concept Type of "00003", Country Code of "01", and Type Code of "1", the following would be retrieved:

Concept Type	Country Code	Concept ID	Type Code	Description
00003	01	000007600	1	Imitrex Nasal Solution
00003	01	0000008607	1	Imitrex Injection Solution
00003	01	0000017400	1	Imitrex Oral Tablet
00003	01	0000030591	1	Imitrex Subcutaneous Kit
00003	01	0000030592	1	Imitrex Subcutaneous Solution

# Retrieving Dose Form Drug(s) for a Drug Name

Follow the steps below to retrieve the Dose Form Drug(s) associated with a Drug Name.

 Using the Drug Name and its associated Type Code, retrieve the Concept ID from the Description File. The Concept Type for a Drug Name is 00001. The Country Code is 01 USA.

### Example:

Using the Drug Name of "Imitrex", Type Code of "1", Concept Type of "00001", and Country Code of "01", the following would be retrieved:

Concept Type	Country Code	Concept ID	Type Code	Description
00001	01	0000005749	1	Imitrex

2. The Concept ID in the Description File represents a Drug Name. Therefore, it is treated as the Drug Name ID in the Drug Dose Form File. Using the Concept ID from Step 1 as the Drug Name ID, retrieve all corresponding records in the Drug Dose Form File. The Concept Type for a Dose Form Drug is 00221. The Country Code is 01 USA.

Using the Drug Name ID of "0000005749", Concept Type of "00221", and Country Code of "01" the following would be retrieved:

Concept Type	Country Code	Concept ID	Drug Name ID	Dose Form ID	Status
00221	01	0000008314	0000005749	00043	3
00221	01	0000008315	0000005749	00070	1
00221	01	0000008316	0000005749	00081	1

3. For each record obtained in Step 2, use the Concept ID and desired Type Code to retrieve the associated Description for the Dose Form Drug from the Description File. The Concept Type for a Dose Form is 00221. The Country Code is 01 USA.

### Example:

Using the Concept IDs of "0000008314", "0000008315", and "0000008316", Concept Type of "00221", Country Code of "01", and Type Code of "1", the following would be retrieved:

Concept Type	Country Code	Concept ID	Type Code	Description
00221	01	0000008314	1	Imitrex Kit
00221	01	0000008315	1	Imitrex Solution
00221	01	0000008316	1	Imitrex Tablet

# Retrieving Dispensable Drug(s) for a Drug Name

Follow the steps below to retrieve the Dispensable Drug(s) associated with a Drug Name.

1. Using the Drug Name and its associated Type Code, retrieve the Concept ID from the Description File. The Concept Type for a Drug Name is 00001. The Country Code is 01 USA.

### Example:

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Using the Drug Name of Imitrex", Type Code of "1", Concept Type of "00001", and Country Code of "01", the following would be retrieved:

Concept Type	Country Code	Concept ID	Type Code	Description
00001	01	0000005749	1	Imitrex

2. The Concept ID in the Description File represents a Drug Name. It is treated as the Drug Name ID in the Routed Drug File. Using the Concept ID from Step 1 as the Drug Name ID, retrieve all corresponding records in the Routed Drug File. The Concept Type for a Routed Drug is 00002. The Country Code is 01 USA.

### Example:

Using the Drug Name ID of "0000005749", Concept Type of "00002", and Country Code of "01" the following would be retrieved:

Concept Type	Country Code	Concept ID	Drug Name ID	Route ID	Status
00002	01	0000005839	0000005749	00022	1
00002	01	0000006651	0000005749	00009	4
00002	01	0000013643	0000005749	00024	1
00002	01	0000025763	0000005749	00028	1

3. The Concept ID in the Routed Drug File represents a Routed Drug. It is treated as the Routed Drug ID in the Dispensable Drug File. Using the Concept ID from Step 2 as the Routed Drug ID, retrieve all corresponding records in the Dispensable Drug File. The Concept Type for a Dispensable Drug is 00004. The Country Code is 01 USA.

### Example:

Using the Routed Drug IDs of "0000005839", "0000006651", "0000013643", and "0000025763", Concept Type of "00004", and Country Code of "01", the following would be retrieved:

Concept Type	Country Code	Concept ID	Routed Drug ID	Dose Form ID	Str	Str Uom	Name Source	Device Flag	Statu s	Link Value	Link Date
00004	01	0000052822	0000005839	00070	5	MG/ACT	1	0	1		
00004	01	0000052823	0000005839	00070	20	MG/ACT	1	0	1		
00004	01	0000010586	0000006651	00070	6	MG/0.5ML	1	0	4	0000141849	20090326
00004	01	0000040964	0000013643	00081	25	MG	1	1	1		
00004	01	0000040965	0000013643	00081	50	MG	1	0	1		
00004	01	0000068073	0000013643	00081	100	MG	1	0	1		
00004	01	0000075119	0000025763	00043	6	MG/0.5ML	1	0	3		
00004	01	0000141849	0000025763	00070	6	MG/0.5ML	1	0	1		

Note

The Dose Form ID is not the same value as the Dosage Form in the Drug Name File. Refer to Associating Dosage Form in the Drug Name File to Dose Form in the Description File for information.

Note

The Link Value and Link Date indicate that the Concept ID has been replaced by the Concept ID defined by the Link Value. Depending on the needs of your application, retrieval of the Dispensable Drug record for the Concept ID defined by the Link Value may be necessary. In this example, the record was returned.

Note

Additional attributes are associated with these records, but are excluded here due to space constraints.

4. For each record obtained in Step 3, use the Concept ID and desired Type Code to retrieve the associated Description in the Description File. The Concept Type for a Dispensable Drug is 00004. The Country Code is 01 USA.

### Example:

Using the Concept IDs from Step 3, Concept Type of "00004", Country Code of "01", and Type Code of "1", the following would be retrieved:

Concept Type	Country Code	Concept ID	Type Code	Description
00004	01	0000052822	1	Imitrex Nasal Solution 5 MG/ ACT
00004	01	0000052823	1	Imitrex Nasal Solution 20 MG/ACT
00004	01	0000010586	1	Imitrex Injection Solution 6 MG/0.5ML
00004	01	0000040964	1	Imitrex Oral Tablet 25 MG
00004	01	0000040965	1	Imitrex Oral Tablet 50 MG
00004	01	0000068073	1	Imitrex Oral Tablet 100 MG
00004	01	0000075119	1	Imitrex Subcutaneous Kit 6 MG/0.5ML
00004	01	0000141849	1	Imitrex Subcutaneous Solution 6 MG/0.5ML

# Retrieving Routed Dose Form Drug(s) for a Routed Drug

To retrieve Routed Dose Form Drug(s) for a Routed Drug, refer to Steps 3 and 4 in Retrieving Routed Dose Form Drug(s) for a Drug Name.

# Retrieving Dispensable Drug(s) for a Routed Drug

To retrieve Dispensable Drug(s) for a Routed Drug, refer to Steps 3 and 4 in Retrieving Dispensable Drug(s) for a Drug Name.

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# Retrieving Dispensable Drug(s) for a Routed Dose Form Drug

Follow the steps below to retrieve the Dispensable Drug(s) associated with a Routed Dose Form Drug.

 Using the Routed Dose Form Drug and its associated Type Code, retrieve the Concept ID from the Description File. The Concept Type for a Routed Dose Form Drug is 00003. The Country Code is 01 USA.

### Example:

Using the Routed Dose Form Drug of "Imitrex Oral Tablet", Type Code of "1", Concept Type of "00003", and Country Code of "01", the following would be retrieved:

Concept Type	Country Code	Concept ID	Type Code	Description
00003	01	0000017400	1	Imitrex Oral Tablet

2. The Concept ID in the Description File represents a Routed Dose Form Drug. Therefore, it is treated as the Routed Drug Form ID in the Dispensable Drug File. Using the Concept ID from Step 1 as the Routed Drug Form ID, retrieve all corresponding records in the Dispensable Drug File. The Concept Type for a Dispensable Drug is 00004. The Country Code is 01 USA.

### Example:

Using the Routed Drug ID of "0000017400", Concept Type of "00004", and Country Code of "01", the following would be retrieved:

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Concept Type	Country Code	Concept ID	Routed Drug ID	Dose Form ID	Str	Str Uom	Name Source	Device Flag	Status	Link Value	Link Date
00004	01	0000040964	0000017400	00081	25	MG	1	1	1		
00004	01	0000040965	0000017400	00081	50	MG	1	0	1		
00004	01	0000068073	0000017400	00081	100	MG	1	0	1		

Note	The Dose Form ID is not the same value as the Dosage Form in the Drug Name File. Refer to
	Associating Dosage Form in the Drug Name File to Dose Form in the Description File for
	information.

Note	Additional attributes are associated with these records, but are excluded here due to space
	constraints.

3. For each record obtained in Step 2, use the Concept ID and desired Type Code to retrieve the associated Description in the Description File. The Concept Type for a Dispensable Drug is 00004. The Country Code is 01 USA.

### Example:

Using the Concept IDs from Step 2, Concept Type of "00004", Country Code of "01", and Type Code of "1", the following would be retrieved:

Concept Type	Country Code	Concept ID	Type Code	Description
00004	01	0000040964	1	Imitrex Oral Tablet 25 MG
00004	01	0000040965	1	Imitrex Oral Tablet 50 MG
00004	01	0000068073	1	Imitrex Oral Tablet 100 MG

# Retrieving Dispensable Drug(s) for a Dose Form Drug

Follow the steps below to retrieve the Dispensable Drug(s) associated with a Dose Form Drug.

1. Using the Dose Form Drug and its associated Type Code, retrieve the Concept ID from the Description File. The Concept Type for a Dose Form Drug is 00221. The Country Code is 01 USA.

### Example:

Using the Dose Form Drug of "Imitrex Tablet", Type Code of "1", Concept Type of "00221", and Country Code of "01", the following would be retrieved:

Concept Type	Country Code	Concept ID	Type Code	Description
00221	01	0000008316	1	Imitrex Tablet

2. The Concept ID in the Description File represents a Dose Form Drug. Therefore, it is treated as the Drug-Dose Form ID in the Dispensable Drug File. Using the Concept ID from Step 1 as the Drug-Dose Form ID, retrieve all corresponding records in the Dispensable Drug File. The Concept Type for a Dispensable Drug is 00004. The Country Code is 01 USA.

### Example:

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Using the Drug-Dose Form ID of "0000008316", Concept Type of "00004", and Country Code of "01", the following would be retrieved:

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Concept Type	Country Code	Concept ID	Routed Drug ID	Dose Form ID	Str	Str Uom	Name Source	Device Flag	Status	Drug-Dose Form ID
00004	01	0000040964	0000013643	00081	25	MG	1	1	1	0000008316
00004	01	0000040965	0000013643	00081	50	MG	1	0	1	0000008316
00004	01	0000068073	0000013643	00081	100	MG	1	0	1	0000008316

Note	The Dose Form ID is not the same value as the Dosage Form in the Drug Name File. Refer to
	Associating Dosage Form in the Drug Name File to Dose Form in the Description File for
	information.

Note	Additional attributes are associated with these records, but are excluded here due to space
	constraints.

3. For each record obtained in Step 2, use the Concept ID and desired Type Code to retrieve the associated Description in the Description File. The Concept Type for a Dispensable Drug is 00004. The Country Code is 01 USA.

### Example:

Using the Concept IDs from Step 2, Concept Type of "00004", Country Code of "01", and Type Code of "1", the following would be retrieved:

Concept Type	Country Code	Concept ID	Type Code	Description
00004	01	0000040964	1	Imitrex Oral Tablet 25 MG
00004	01	0000040965	1	Imitrex Oral Tablet 50 MG
00004	01	0000068073	1	Imitrex Oral Tablet 100 MG

# **Associating Brand and Generic Drug Names**

Follow the steps below to associate brand and generic Drug Names.

### **Identifying a Generic Name for a Brand Name**

 Drugs names for a "brand" can be identified by their Name Type in the SDI Name File. In this case, Name Types of either 1 - Trademarked or 2 - Brand Name may be considered. Using the available Drug Name (either Trademarked or Brand) and its associated Type Code, retrieve the Concept ID from the Description File. The Concept Type for a Drug Name is 00001. The Country Code is 01 USA.

### Example:

Using the Drug Name of "Imitrex", Type Code of "1", Concept Type of "00001", and Country Code of "01", the following would be retrieved:

Concept Type	Country Code	Concept ID	Type Code	Description
00001	01	0000005749	1	Imitrex

2. Using the Concept ID from Step 1, retrieve all corresponding records in the Reference Name File. The Concept Type for a Drug Name is 00001. The Country Code is 01 USA.

Using the Concept ID of "0000005749", Concept Type of "00001", and Country Code of "01", the following would be retrieved:

Concept Type	Country Code	Concept ID		Medi-Span Refer- ence Flag
00001	01	0000005749	0000000303	Υ

3. The ID for Generic Named Drug represents a Concept ID. Using the ID for Generic Named drugs as a Concept ID, retrieve the associated Description from the Description File. The Concept Type for a Drug Name is 00001. The Country Code is 01 USA.

### Example:

Using the Concept ID of "0000000303", Concept Type of "00001", and Country Code of "01", the following would be retrieved:

Concept Type	Country Code	Concept ID	Type Code	Description
00001	01	0000000303	1	SUMatriptan

You can now associate the two names as required by your application such as:

- Drug lists or picklists
- Prescription drug labeling
- **eMARs**
- others

### Examples include:

- Imitrex (SUMatriptan)
- SUMatriptan (Imitrex)

Note

The above example includes Tall Man lettering for SUMatriptan. Tall Man letters provided by Wolters Kluwer Clinical Drug Information should be maintained in your application and presented in all instances, whether in a visual display or a hard copy report.

# **Identifying a Brand Name for a Generic Name**

1. Drugs names for a "generic" can be identified by their Name Type in the SDI Name File. In this case, Name Type of 3 - Generic is relevant. Using the

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available Drug Name and its associated Type Code, retrieve the Concept ID from the Description File. The Concept Type for a Drug Name is 00001. The Country Code is 01 USA.

### Example:

Using the Drug Name of "Verapamil HCI", Type Code of "1", Concept Type of "00001", and Country Code of "01", the following would be retrieved:

Concept Type	Country Code	Concept ID	Type Code	Description
00001	01	0000009666	1	Verapamil HCI

 The Concept ID for this generic Drug Name represents the ID for Generic Named Drug in the Reference Name File. Using the Concept ID from Step 1 as the ID for Generic Named Drug, retrieve all corresponding records in the Reference Name File. The Concept Type for a Drug Name is 00001. The Country Code is 01 USA.

### Example:

Using the Concept ID of "0000009666" as the ID for Generic Named Drug, Concept Type of "00001", and Country Code of "01", the following would be retrieved:

Concept Type	Country Code	Concept ID	ID for Generic Named Drug	Medi-Span Reference Flag
00001	01	000000189	0000009666	N
00001	01	000000701	0000009666	Υ
00001	01	000000704	0000009666	Υ
00001	01	0000008300	0000009666	Υ

3. Using the Concept ID(s) from Step 2, retrieve the associated Description from the Description File. The Concept Type for a Drug Name is 00001. The Country Code is 01 USA.

### Example:

Using the Concept IDs above, Concept Type of "00001", and Country Code of "01", the following would be retrieved:

Concept Type	Country Code	Concept ID	Type Code	Description
00001	01	000000189	1	Verapamil HCI CR
00001	01	000000701	1	Calan SR
00001	01	000000704	1	Isoptin SR
00001	01	0000008300	1	Verelan

The Reference Name File includes the Medi-Span Reference Flag, indicating the reference brand names that have the same 14-character GPI value. There may be zero, one, or many brand names designated as the reference name(s). In the example above, Concept ID 0000000189 is not considered a reference brand name. Therefore, you should exclude it from consideration when identifying brand names for a generic name.

You can now associate the two names as required by your application such as:

- Drug lists or picklists
- Prescription drug labeling
- **eMARs**
- others

### Examples include:

- Calan SR (Verapamil HCI)
- Isoptin SR (Verapamil HCI)
- Verelan (Verapamil HCI)
- Verapamil HCI (Calan SR)
- Verapamil HCI (Isoptin SR)
- Verapamil HCI (Verelan)

# **Associating Brand and Generic Routed Drugs**

Follow the steps below to associate brand and generic Routed Drugs.

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### Identifying a Generic Routed Drug for a Brand Routed Drug

1. Drug names for a "brand" can be identified by their Name Type in the SDI Name File. In this case, Name Types of either 1 - Trademarked or 2 - Brand Name may be considered. Therefore, you must first determine if the Routed Drug you have is considered a "brand". Using the available Routed Drug and its associated Type Code, retrieve the Concept ID from the Description File. The Concept Type for a Routed Drug is 00002. The Country Code is 01 USA.

### Example:

Using the Routed Drug of "Vytorin Oral", Type Code of "1", Concept Type of "00002", and Country Code of "01", the following would be retrieved:

Concept Type	Country Code	Concept ID	Type Code	Description
00002	01	0000031549	1	Vytorin Oral

2. Using the Concept ID from Step 1, retrieve the Drug Name ID for the Routed Drug from the Routed Drug File. The Concept Type for a Routed Drug is 00002. The Country Code is 01 USA.

### Example:

Using the Concept ID of "0000031549", Concept Type of "00002", and Country Code of "01", the following would be retrieved:

Concept Type	Country Code	Concept ID	Drug Name ID	Route ID	Status
00002	01	0000031549	0000030139	24	1

3. The Drug Name ID represents the Concept ID in the SDI Drug Name File. Using the Drug Name ID from Step 2 as input, retrieve the Name Type from the SDI Name File. The Concept Type for a Drug Name is 00001. The Country Code is 01 USA.

### Example:

Documentation Manual 5-27 Published: 11/11 Using the Concept ID of "0000031039", Concept Type of "00001", and Country Code of "01", the following would be retrieved:

Concept Type	Country Code	Concept ID	Name Type	Status
00001	01	0000030139	1	1

The Name Type of 1 indicates that the Drug Name is Trademarked. Therefore, it is reasonable to proceed to identify the associated generically-named Routed Drug.

4. Using the Concept ID for the Routed Drug from Step 1 as input, retrieve all corresponding records in the Reference Name File. The Concept Type for a Routed Drug is 00002. The Country Code is 01 USA.

#### Example:

Using the Concept ID of "0000031549", Concept Type of "00002", and Country Code of "01", the following would be retrieved:

Concept Type	Country Code	Concept ID	ID for Generic Named Drug	Medi-Span Reference Flag
00002	01	0000031549	0000031550	Υ

5. Using the ID for Generic Named drugs as a Concept ID, retrieve the associated Description from the Description File. The Concept Type for a Routed Drug is 00002. The Country Code is 01 USA.

### Example:

Using the Concept ID of "0000031550", Concept Type of "00002", and Country Code of "01", the following would be retrieved:

Concept Type	Country Code	Concept ID	Type Code	Description
00002	01	0000031550	1	Ezetimibe-Simvastatin Oral

The Reference Name File includes the Medi-Span Reference Flag, indicating the reference brand names that have the same 14-character GPI value. There may be zero, one, or many brand names designated as the reference name(s). In this example, Vytorin Oral (Concept ID 0000031549) is considered a reference brand.

You can now associate the two names as required by your application such as:

- Drug lists or picklists
- Prescription drug labeling
- eMARs
- others

### Examples include:

- Vytorin Oral (Ezetimibe-Simvastatin Oral)
- Ezetimibe-Simvastatin Oral (Vytorin Oral)

### Identifying a Brand Routed Drug for a Generic Routed Drug

- Drugs names for a "generic" can be identified by their Name Type in the SDI Name File. In this case, Name Type of 3 Generic is relevant. Therefore, you must first determine if the Routed Drug you have is considered a "generic". Using the available Routed Drug and its associated Type Code, retrieve the Concept ID from the Description File. The Concept Type for a Routed Drug is 00002. The Country Code is 01 USA.
- 2. Using the Concept ID from Step 1, retrieve the Drug Name ID for the Routed Drug from the Routed Drug File. The Concept Type for a Routed Drug is 00002. The Country Code is 01 USA.
- 3. The Drug Name ID represents the Concept ID in the SDI Drug Name File. Using the Drug Name ID from Step 2 as input, retrieve the Name Type from the SDI Name File. The Concept Type for a Drug Name is 00001. The Country Code is 01 USA.

The Name Type of 3 indicates that the Drug Name is Generic. Therefore, it is reasonable to proceed to identify the associated brand-named Routed Drug.

- 4. The Concept ID from Step 1 represents the ID for Generic Named Drug in the Reference Name File. Using the Concept ID as the ID for Generic Named Drug, retrieve all corresponding records in the Reference Name File. The Concept Type for a Routed Drug is 00002. The Country Code is 01 USA.
- 5. Using the ID for Generic Named drugs as a Concept ID, retrieve the associated Description from the Description File. The Concept Type for a Routed Drug is 00002. The Country Code is 01 USA.

The Reference Name File includes the Medi-Span Reference Flag, indicating the reference brand names that have the same 14-character GPI value. There may be zero, one, or many brand names designated as the reference name(s). You should exclude records with a value of "N - Is not a reference brand name" from consideration when identifying brand Routed Drugs for a generic Routed Drug.

Documentation Manual 5-29 Published: 11/11 You can then proceed to associate the two names as needed in your application, as noted in the previous examples.

# **Associating Brand and Generic Dispensable Drugs**

Follow the steps below to associate brand and generic Dispensable Drugs.

# Identifying a Generic Dispensable Drug for a Brand Dispensable Drug

1. Drugs names for a "brand" can be identified by their Name Type in the SDI Name File. In this case, Name Types of either 1 - Trademarked or 2 - Brand Name may be considered. Therefore, you must first determine if the Dispensable Drug you have is considered a "brand". Using the available Dispensable Drug and its associated Type Code, retrieve the Concept ID from the Description File. The Concept Type for a Dispensable Drug is 00004. The Country Code is 01 USA.

### Example:

Using the Dispensable Drug of "Omnaris Nasal Suspension 50 MCG/ACT", Type Code of "1", Concept Type of "00004", and Country Code of "01", the following would be retrieved:

Concept Type	Country Code	Concept ID	Type Code	Description
00004	01	0000133855	1	Omnaris Nasal Suspension 50 MCG/ACT

2. Using the Concept ID from Step 1, retrieve the Routed Drug ID from the Dispensable Drug File. The Concept Type for a Dispensable Drug is 00004. The Country Code is 01 USA.

### Example:

Using the Concept ID of "0000133855", Concept Type of "0004", and Country Code of "01", the following would be retrieved:

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Concept Type	Country Code	Concept ID	Routed Drug ID	Dose Form ID	Str	Str Uom	Name Source	Device Flag	Status	Link Value	Link Date
00004	01	0000133855	0000005688	00077	50	MCG/ACT	1	0	1		

Note	The Dose Form ID is not the same value as the Dosage Form in the Drug Name File. Refer to
	Associating Dosage Form in the Drug Name File to Dose Form in the Description File for
	information.

Note	Additional attributes are associated with these records, but are excluded here due to space
	constraints.

3. The Routed Drug ID in the Dispensable Drug File represents the Concept ID in the Routed Drug File. Using the Routed Drug ID from Step 2 as the Concept ID, retrieve the Drug Name ID from the Routed Drug File. The Concept Type for a Routed Drug is 00002. The Country Code is 01 USA.

#### Example:

Using the Routed Drug ID of "0000005688", Concept Type of "00002", and Country Code of "01", the following would be retrieved:

Concept Type	Country Code	Concept ID	Drug Name ID	Route ID	Status
00002	01	0000005688	0000005602	24	2

4. The Drug Name ID represents the Concept ID in the SDI Drug Name File. Using the Drug Name ID from Step 3 as input, retrieve the Name Type from the SDI Name File. The Concept Type for a Drug Name is 00001. The Country Code is 01 USA.

#### Example:

Using the Concept ID of "0000005602", Concept Type of "00001", and Country Code of "01", the following would be retrieved:

Concept Type	Country Code	Concept ID	Name Type	Status
00001	01	0000005602	2	2

The Name Type of 2 indicates that the Drug Name is a Brand Name. Therefore, it is reasonable to proceed to identify the associated generically-named Dispensable Drug.

5. Using the Concept ID for the Dispensable Drug from Step 1 as input, retrieve all corresponding records in the Reference Name File. The Concept Type for a Dispensable Drug is 00004. The Country Code is 01 USA.

#### Example:

Using the Concept ID of "00000133855", Concept Type of "00004", and Country Code of "01", the following would be retrieved:

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Concept	Country	Concept ID	ID for Generic	Medi-Span
Type	Code		Named Drug	Reference Flag
00004	01	00000133855	0000122782	Υ

6. Using the ID for Generic Named Drug from Step 5 as a Concept ID, retrieve the associated Description from the Description File. The Concept Type for a Dispensable Drug is 00004. The Country Code is 01 USA.

#### Example:

Using the Concept ID of "00000122782", Concept Type of "00004", and Country Code of "01", the following would be retrieved:

Concept Type	Country Code	Concept ID	Type Code	Description
00004	01	0000122782	1	Ciclesonide Nasal Suspension 50 MCG/ACT

The Reference Name File includes the Medi-Span Reference Flag, indicating the reference brand names that have the same 14-character GPI value. There may be zero, one, or many brand names designated as the reference name(s). In this example, Omnaris Nasal Suspension 50 MCG/ACT (Concept ID 0000133855) is considered a reference brand.

You can now associate the two names as required by your application such as:

- Drug lists or picklists
- Prescription drug labeling
- eMARs
- or others

#### Examples include:

- Omnaris Nasal Suspension 50 MCG/ACT (Ciclesonide Nasal Suspension 50 MCG/ACT)
- Ciclesonide Nasal Suspension 50 MCG/ACT (Omnaris Nasal Suspension 50 MCG/ACT)

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# Identifying a Brand Dispensable Drug for an Generic Dispensable Drug

- 1. Drugs names for a "generic" can be identified by their Name Type in the SDI Name File. In this case, Name Type of 3 Generic is relevant. Therefore, you must first determine if the Dispensable Drug you have is considered a "generic". Using the available Dispensable Drug and its associated Type Code, retrieve the Concept ID from the Description File. The Concept Type for a Dispensable Drug is 00004. The Country Code is 01 USA.
- 2. Using the Concept ID from Step 1, retrieve the Routed Drug ID from the Dispensable Drug File. The Concept Type for a Dispensable Drug is 00004. The Country Code is 01 USA.
- 3. The Routed Drug ID in the Dispensable Drug File represents the Concept ID in the Routed Drug File. Using the Routed Drug ID from Step 2 as the Concept ID, retrieve the Drug Name ID from the Routed Drug File. The Concept Type for a Routed Drug is 00002. The Country Code is 01 USA.
- 4. The Drug Name ID represents the Concept ID in the SDI Drug Name File. Using the Drug Name ID from Step 3 as input, retrieve the Name Type from the SDI Name File. The Concept Type for a Drug Name is 00001. The Country Code is 01 USA.

The Name Type of 3 indicates that the Drug Name is Generic. It is reasonable to proceed to identify the associated brand-named Dispensable Drug.

- 5. The Concept ID from Step 1 represents the ID for Generic Named Drug in the Reference Name File. Using the Concept ID as the ID for Generic Named Drug as input, retrieve all corresponding records in the Reference Name File. The Concept Type for a Dispensable Drug is 00004. The Country Code is 01 USA.
- 6. Using the Concept ID from Step 5, retrieve the associated Description from the Description File. The Concept Type for a Dispensable Drug is 00004. The Country Code is 01 USA.

The Reference Name File includes the Medi-Span Reference Flag, indicating the reference brand names that have the same 14-character GPI value. There may be zero, one, or many brand names designated as the reference name(s). You should exclude records with a value of "N - Is not a reference brand name" from consideration when identifying a brand Dispensable Drugs for a generic Dispensable Drug.

You can then proceed to associate the two names as needed in your application, as noted in the previous examples.

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# **Constructing Alternative Drug Names**

There are several alternative drug names that can be constructed using the Reference Name File and the Description File. In some cases, you may also wish to construct drug names with varying degrees of specificity by navigating the Routed Drug File and Dispensable Drug File with the algorithms above to identify the desired Concept ID(s) and then using the Reference Name File and the Description File.

The following information provides a few of several options for constructing Alternative Drug Names.

#### **Constructing BRAND NAME (generic name)**

Follow the steps defined in Identifying a Brand Name for a Generic Name or Identifying a Generic Name for a Brand Name".

 Using the Description File, retrieve the capitalized name for the Concept ID representing the brand name. The Concept Type for a Drug Name is 00001. The Type Code for Capitalized Name is 3. The Country Code is 01 USA.

#### Example:

Using the Concept ID "0000005749", Concept Type "00001", Type Code "3", and Country Code "01", the following would be retrieved:

Concept Type	Country Code	Concept ID	Type Code	Description
00001	01	0000005749	3	IMITREX

2. Using the Description File, retrieve the salt name for the Concept ID representing the generic name. The Concept Type for a Drug Name is 0001. The Type Code for Salt Name is 4. The Country Code is 01 USA.

#### Example:

Using the Concept ID "0000000303", Concept Type "00001", Type Code "4", and Country Code "01", the following would be retrieved:

Concept Type	Country Code	Concept ID	Type Code	Description
00001	01	000000303	4	SUMatriptan

You can now associate the two names as required by your application such as:

- Drug lists or picklists
- Prescription drug labeling
- eMARs
- or others

#### Examples include:

- IMITREX (SUMatriptan)
- SUMatriptan (IMITREX)

#### Note

The above example includes Tall Man lettering for SUMatriptan. Tall Man letters provided by Wolters Kluwer Clinical Drug Information should be maintained in your application and presented in all instances, whether in a visual display or a hard copy report.

# Presenting a Dispensable Drug with an Alternate Dose Form Representation

1. Using the Concept ID for a Dispensable Drug, retrieve the corresponding record from the Dispensable Drug File. The Concept Type for a Dispensable Drug is 00004. The Country Code is 01 USA.

#### Example:

Using the Concept ID of "0000017675", Concept Type of "00004", and Country Code of "01", the following would be retrieved:

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Concept Type	Country Code	Concept ID	Routed Drug ID	Dose Form ID	Str	Str Uom	Name Source	Device Flag	Status	Link Value	Link Date
00004	01	0000017675	0000009584	00014	20	MG	1	0	1		

Note	The Dose Form ID is not the same value as the Dosage Form in the Drug Name File. Refer to
	Associating Dosage Form in the Drug Name File to Dose Form in the Description File for
	information.

**Note** Additional attributes are associated with these records, but are excluded here due to space constraints.

2. The Dose Form ID in the Dispensable Drug File represents a Concept ID in the Description File. Using the Dose Form ID from Step 1 as a Concept ID, retrieve the corresponding description from the Description File. The Concept Type for a Dose Form is 00009. The Country Code is 01 USA.

Note

The Dose Form in the Dispensable Drug File is five digits. The Concept ID for a Dose Form in the Description File is 10 digits. The significant digits in the two values are the same.

#### Example:

Using the Dose Form ID of "00014" as the Concept ID of "0000000014", Concept Type of "00009", and Country Code of "01", the following would be retrieved:

Concept Type	Country Code	Concept ID	Type Code	Description
00009	01	000000014	1	Capsule Delayed Release
00009	01	000000014	2	CPDR
00009	01	000000014	5	Enteric Coated Capsule

The "standard" Dose Form representation associated to a DDID in the Description File is based on Type Code 1.

Note

The Abbreviated Textual Description (Type Code 2) for a Dose Form is provided to enable developers to associate a Dosage Form value in the Drug Name File to a Dose Form value in the Description File. The Abbreviated Textual Description for a Dose Form is not to be displayed or provided in print form in end-user applications. Significant patient safety issues are associated with the use of nonstandard Dose Form abbreviations. An example for Associating Dosage Form in the Drug Name File to Dose Form in the Description File follows later in this chapter.

In this example, the "standard" representation for Dose Form 00014 or 000000014 is "Capsule Delayed Release". Using the Alternate Name (Type Code 5) to represent the Dose Form, "Enteric Coated Capsule" would result.

#### Example:

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Concept Type	Drug Name	Route	Dosage Form	Strength	Strength UOM
0000017675	PriLOSEC	Oral	Capsule Delayed Release	20	MG
0000017675	PriLOSEC	Oral	Enteric Coated Capsule	20	MG

# Presenting a Dispensable Drug with an Alternate Strength-Strength UOM Representation

Using the Concept ID for a Dispensable Drug, retrieve the corresponding record from the Dispensable Drug File. The Concept Type for a Dispensable Drug is 00004. The Country Code is 01 USA.

#### Example:

Using the Concept ID of "0000088732", Concept Type of "00004", and Country Code of "01", the following would be retrieved:

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Concept Type	Country Code	Concept ID	Routed Drug ID	Dose Form ID	Str	Str Uom	Name Source	Device Flag	Status	Strength-Strength UOM ID
00004	01	0000088732	0000031549	00081	10-10	MG	1	0	1	000002432

Note The Dose Form ID is not the same value as the Dosage Form in the Drug Name File. Refer to Associating Dosage Form in the Drug Name File to Dose Form in the Description File for information.

**Note** Additional attributes are associated with these records, but are excluded here due to space constraints.

5-40 MED-File v2 Published: 11/11  The Strength-Strength UOM ID in the Dispensable Drug File represents a Concept ID in the Description File. Using the Strength-Strength UOM ID from Step 1 as a Concept ID, retrieve the corresponding description from the Description File. The Concept Type for a Strength-Strength UOM ID is 00222. The Country Code is 01 USA.

#### Example:

Using the Concept ID of "0000002432", Concept Type of "00222", and Country Code of "01", the following would be retrieved:

Concept Type	Country Code	Concept ID	Type Code	Description
00222	01	0000002432	1	10-10 MG
00222	01	0000002432	5	10 mg - 10 mg

The "standard" Strength-Strength UOM representation associated to a DDID in the Description File is based on Type Code 1.

In this example, the "standard" representation for Strength-Strength UOM is "10-10 MG". Using the Alternate Name (Type Code 5) to represent the Strength-Strength UOM, "10 mg - 10 mg" would result.

#### Example:

Concept Type	Drug Name	Route	Dosage Form	Strength-Strength UOM
0000088732	Vytorin	Oral	Tablet	10-10 MG
0000088732	Vytorin	Oral	Tablet	10 mg - 10 mg

# Associating Dosage Form in the Drug Name File to Dose Form in the Description File

The Dosage Form field in the Drug Name file is defined by a four-character code. This code is not intended for use in end-user applications and must be translated to its description using the Validation/Translation File.

#### Examples include:

Dosage Form	Description
CAPS	Capsule
CHEW	Tablet Chewable
CP12	Capsule Extended Release 12 Hour
LQCR	Liquid Extended Release
PT24	Patch 24 Hour

The Dose Form ID in the Description File is defined by a five-digit value. The value itself has no meaning. The value must be translated to its description using the Description File. The Concept ID in the Description file is a 10-digit value. The significant digits of the five-digit Dose Form ID are the same as those in the 10-digit Concept ID.

Note	The five-digit Dose Form ID is an attribute in the Dispensable Drug File, the
	Drug-Dose Form File, and the Routed Drug Form File.

There are three types of descriptions for Dose Forms in the Description File:

- Full Textual Description (Type Code 1)
- Abbreviated Textual Description (Type Code 2)
- Alternate Name (Type Code 5)

The Concept Type for a Dose Form is 00009. The Country Code is 01 USA.

5-42 MED-File v2 Published: 11/11 Examples of Dose Form IDs and their associated Concept IDs and descriptions include:

Dose Form ID	Concept ID	Concept Type	Type Code	Description	
00008	800000000	00009	01	Capsule	
00008	0000000008	00009	02	CAPS	
00008	0000000008	00009	05	Capsule	
00009	000000009	00009	01	Tablet Chewable	
00009	000000009	00009	02	CHEW	
00009	000000009	00009	05	Chewable Tablet	
00011	000000011	00009	01	Capsule Extended Release 12 Hour	
00011	0000000011	00009	02	CP12	
00011	000000011	00009	05	12 Hour Extended Release Capsule	
00049	000000049	00009	01	Liquid Extended Release	
00049	000000049	00009	02	LOCR	
00049	000000049	00009	05	Extended Release Liquid	
00061	0000000061	00009	01	Patch 24 Hour	
00061	0000000061	00009	02	PT24	
00061	0000000061	00009	05	24 Hour Transdermal Patch	

The Dosage Form can be associated to the Dose Form in one of two ways:

- By a textual match of the Value Description for the Dosage Form in the Validation/Translation File to the record in the Description File with a Type Code of 01 (Full Textual Description).
- By a match of the Dosage Form value in the Drug Name File or the Validation/Translation File to the record in the Description File with a Type Code of 02 (Abbreviated Textual Description).

#### Examples include:

Dose Form	Dose Form ID	Concept ID	Concept Type	Type Code	Description
CAPS	00008	800000000	00009	02	CAPS
CHEW	00009	000000009	00009	02	CHEW
CP12	00011	000000011	00009	02	CP12
LQCR	00049	000000049	00009	02	LQCR
PT24	00061	0000000061	00009	02	PT24

As already stated, the Abbreviated Textual Description for a Dose Form is not intended for use in end-user applications. Either the Full Textual Description or the Alternate Name should be used.

# Associating Route of Administration in the Drug Name File to Route in the Description File

The Route of Administration Code in the Drug Name file is defined by a 2-character code. This code is not intended for use in end-user applications and must be translated to its description using the Validation/Translation File.

#### Examples include:

Route of Administration Code	Description
СО	Combination
IJ	Injection
IX	Intra-articular

The Route ID is five-digit value. The value itself has no meaning. The value must be translated to its description using the Description File. The Concept ID in the Description file is a 10-digit value. The significant digits of the five-digit Route ID are the same as those in the 10-digit Concept ID.

Note	The five-digit Route ID is an attribute in	n the Routed Drug File.

There are two types of descriptions for Routes in the Description File:

Full Textual Description (Type Code 1)

5-44 MED-File v2 Published: 11/11 Abbreviated Textual Description (Type Code 2)

The Concept Type for a Route is 00008. The Country Code is 01 USA.

Examples of Route IDs and their associated Concept IDs and descriptions include:

Route ID	Concept ID	Concept Type	Type Code	Description
00002	0000000002	80000	01	Combination
00002	0000000002	80000	02	СО
00009	000000009	80000	01	Injection
00009	000000009	80000	02	IJ
00020	0000000020	80000	01	Intra-articular
00020	000000020	80000	02	IX

The Route of Administration can be associated to the Route in one of two ways:

- By a textual match of the Value Description for the Route of Administration in the Validation/Translation File to the record in the Description File with a Type Code of 01 (Full Textual Description)
- By a match of the Route of Administration Code in the Drug Name File or the Validation/Translation to the record in the Description File with a Type Code of 02 (Abbreviated Textual Description)

#### Examples include:

Route of Administration Code	Dose Form ID	Concept ID	Concept Type	Type Code	Description
СО	00002	0000000002	00008	02	СО
IJ	00009	000000009	00008	02	IJ
IX	00020	0000000020	80000	02	IX

As already stated, the Abbreviated Textual Description for a Route is not intended for use in end-user applications. The Full Textual Description should be used.

# Identifying Ingredients for a Dispensable Drug

Follow the steps below to identify the ingredients for a Dispensable Drug.

1. Using the Concept ID for the Dispensable Drug, retrieve the Ingredient Set ID from the Drug Concept ID to Ingredient Set ID File. The Concept Type for a Dispensable Drug is 00004. The Country Code is 01 USA.

#### Example:

Using the Concept ID of "089522", Concept Type of "00004", and Country Code of "01", the following would be retrieved:

Concept	Country	Concept ID	Ingredient Set	Representative
Type	Code		ID	Set Indicator
00004	01	089522	0000046458	2

2. Using the Ingredient Set ID from Step 1, retrieve the Ingredient Identifier(s) from the Ingredient Set to Ingredient ID File.

#### Example:

Using the Ingredient Set ID "0000046458", the following would be retrieved:

Ingredient Set ID	Ingredient Identifier	Active/Inactive Flag	
0000046458	0000005825	Α	
0000046458	0000006913	А	

3. Using the Ingredient Identifier(s) from Step 2, retrieve the Ingredient Drug ID from the Ingredient ID to Drug-Strength File.

#### Example:

Using the Ingredient Identifiers of "0000005825" and "0000006913", the following would be retrieved:

Ingredient Identifier	Ingredient Drug ID	Ingredient Strength Value	Ingredient Strength UOM (combined)
0000005825	000000701	0000060000000	MG
0000006913	000000946	0000040000000	UNIT

4. Using the Ingredient Drug ID(s) from Step 3, retrieve the Ingredient Drug Name from the Ingredient Drug File.

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#### Example:

Using the Ingredient IDs of "000000701" and "0000000946", the following would be retrieved:

Ingredient Drug ID	CAS Number	Knowledge Base Drug Code 7	Ingredient Drug Name	Generic ID
000000701	000471341	0020401	CALCIUM CAR- BONATE	C000471341
000000946	001406162	0143501	VITAMIN D	C001406162

5. The data obtained in Steps 2, 3, and 4 can be formatted to present the ingredient name(s) and corresponding strength and strength unit of measure. In addition, ingredients can be noted as "Active" or "Inactive", if desired.

#### Example:

DDID/Description	Ingredient	Strength	Strength UOM	Active or Inactive
089522 Calcium Carbonate-Vita-	CALCIUM CARBONATE	600	MG	Active
min D Oral Tablet 600-400 MG-UNIT	VITAMIN D	400	UNIT	Active

In this example, a representative Ingredient Set is assigned to this DDID as indicated by the Representative Set Indicator of "2" in Step 1. This usually indicates that there are multiple NDCs sharing this DDID and the NDCs are composed of varying ingredients. The variation is usually due to one or more inactive ingredients. The following example illustrates retrieval of ingredients for an NDC-UPC-HRI.

# Identifying Ingredients for an NDC-UPC-HRI

Follow the steps below to identify the ingredients for an NDC-UPC-HRI.

1. Using the NDC-UPC-HRI as the Concept ID, retrieve the Ingredient Set ID from the Drug Concept ID to Ingredient Set ID File. The Concept Type for an NDC-UPC-HRI is 00007. The Country Code is 01 USA.

Example:

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Using the Concept ID of "00904323352", Concept Type of "00007", and Country Code of "01", the following would be retrieved:

	ncept pe	Country Code	Concept ID	Ingredient Set ID	Representative Set Indicator
00	007	01	00904323352	0000068707	1

2. Using the Ingredient Set ID from Step 1, retrieve the Ingredient Identifier(s) from the Ingredient Set to Ingredient ID File.

#### Example:

Using the Ingredient Set ID "0000068707", the following would be retrieved:

Ingredient Set ID	Ingredient Identifier	Active/Inactive Flag
0000068707	0000002563	A
0000068707	0000005825	А
0000068707	0000052064	I

3. Using the Ingredient Identifier(s) from Step 2, retrieve the Ingredient Drug ID from the Ingredient ID to Drug-Strength File.

#### Example:

Using the Ingredient Identifiers of "0000002563", "0000005825" and "0000052064", the following would be retrieved:

Ingredient Identifier	Ingredient Drug ID	Ingredient Strength Value	Ingredient Strength UOM (combined)
0000002563	0000000252	0000040000000	UNIT
0000005825	000000701	0000060000000	MG
0000052064	0000008882	000000000000	

4. Using the Ingredient Drug ID(s) from Step 3, retrieve the Ingredient Drug Name from the Ingredient Drug File.

#### Example:

Using the Ingredient IDs of "000000252", "0000000701" and "0000008882", the following would be retrieved:

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Ingredient Drug ID	CAS Number	Knowledge Base Drug Code 7	Ingredient Drug Name	Generic ID
0000000252	000067970	0298001	CHOLECALCIF- EROL	C000067970
000000701	000471341	0020401	CALCIUM CAR- BONATE	C000471341
0000008882	002783940	1652503	FD&C YELLOW #6 (SUNSET YELLOW)	C002783940

5. The data obtained in Steps 2, 3, and 4 can be formatted to present the ingredient name(s) and corresponding strength and strength unit of measure. In addition, ingredients can be noted as "Active" or "Inactive", if desired.

#### Example:

NDC-UPC-HRI	Ingredient	Strength	Strength UOM	Active or Inactive
00904-3233-52	CALCIUM CARBON- ATE	600	MG	Active
Calcium Carbonate- Vitamin D Oral Tab- let 600-400 MG-	CHOLECALCIF- EROL	400	UNIT	Active
UNIT	FD&C YELLOW #6 (SUNSET YELLOW)			Inactive

This example illustrates an NDC-UPC-HRI that shares the same DDID as the previous example. However, the ingredients include those specific to the drug product, including inactive ingredients.

# **Associating New and Old NDC-UPC-HRIs**

Each NDC-UPC-HRI record in the NDC File includes attributes that enable you to associate it to an old NDC-UPC-HRI and/or a new NDC-UPC-HRI, where appropriate.

When an NDC-UPC-HRI record is added to MED-File v2 for the first time, the following record is provided in the NDC File. These examples include only those fields in the NDC File record that are relevant to this discussion.

NDC-UPC-HRI	Item Status Flag	Old NDC- UPC-HRI	New NDC- UPC-HRI	Old Effective Date	New Effective Date	Transaction Code
12345678901	Α					А

**Note** The Transaction Code field is populated only in Incremental Updates. If you receive a Total Replacement, this field will be blank.

If the NDC-UPC-HRI is replaced by another NDC-UPC-HRI, the following records are provided in the NDC File. These examples include only those fields being discussed here.

NDC-UPC- HRI	Item Status Flag	Old NDC- UPC-HRI	New NDC- UPC-HRI	Old Effective Date	New Effective Date	Transac- tion Code
12345678901	I		45678901234		20081001	С
45678901234	А	12345678 901		20081001		А

Note The Transaction Code field is populated only in Incremental Updates. If you receive a Total Replacement, this field will be blank.

If the NDC-UPC-HRI "45678901234" is subsequently replaced, the following records are provided in the NDC File. These examples include only those fields in the NDC File record that are relevant to this discussion.

NDC-UPC- HRI	Item Sta- tus Flag	Old NDC- UPC-HRI	New NDC- UPC-HRI	Old Effec- tive Date	New Effective Date	Transac- tion Code
12345678901	I		4567890123 4		200081001	
45678901234	I	1234567890 1	7890123456 7	20081001	20100825	С
78901234567	А	4567890123 4		20100825		А

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Note	The Transaction Code field is populated only in Incremental Updates. If you
	receive a Total Replacement, this field will be blank.

Once an NDC-UPC-HRI has been inactive for 48 months, it will be removed from MED-File v2. The following record would appear for NDC-UPC-HRI "12345678901" on the date 20121001. These examples include only those fields in the NDC File record that are relevant to this discussion.

NDC-UPC- HRI	Item Status Flag	Old NDC- UPC-HRI	New NDC- UPC-HRI	Old Effective Date	New Effective Date	Transaction Code
123456789 01	Z		45678901234		200081001	D

Note	This record will appear only once in an Incremental Update. If you receive a
	Total Replacement, the NDC-UPC-HRI record will not appear.

In this example, an NDC-UPC-HRI is replaced by another. In that same MED-File v2 update cycle, the replacement NDC-UPC-HRI is also replaced. The following records are provided in the NDC File. These examples include only those fields in the NDC File record that are relevant to this discussion.

NDC-UPC- HRI	Item Status Flag	Old NDC- UPC-HRI	New NDC- UPC-HRI	Old Effective Date	New Effective Date	Transaction Code
123456789 01	I		45678901234		20008100 1	С
456789012 34	I	123456789 01	78901234567	20081001	20081005	С
789012345 67	А	456789012 34		20081005		А

**Note** The Transaction Code field is populated only in Incremental Updates. If you receive a Total Replacement, this field will be blank.

# Associating New and Old Dispensable Drugs (DDIDs)

Note	The Drug Descriptor Identifier and Dispensable Drug Identifier are one and
	the same. The terms may be used interchangeably in this and other Wolters
	Kluwer Clinical Drug Information documentation.

Each DDID record In the Dispensable Drug File includes attributes that enable you to associate an old Concept ID (DDID) to a new DDID, where appropriate. The Link Value within a record specifies the new DDID replacement. The Link Date indicates when the new DDID replaced the Concept ID.

This example includes only those fields in the Dispensable Drug File record that are relevant to this discussion.

#### Example:

Concept ID	Link Value	Link Date
0000130242	0000164832	20110328

Using the Description File, you can visually examine the differences between the Concept ID for the old DDID and that for the new DDID. The Concept Type for a Dispensable Drug is 00004. The Country Code is 01 USA.

Concept Type	Country Code	Concept Value	Type Code	Description
00004	01	0000130242	01	Fragmin Subcutaneous Injectable 15000 UNIT/0.6ML
00004	01	0000164832	01	Fragmin Subcutaneous Solution 15000 UNIT/0.6ML

The new DDID will also appear in the Drug Name File in field F099 as an attribute of the DDID. This only occurs in the Incremental Update and is not present in the Total Database.

# **Retrieving KDCs for a Dispensable Drug**

The Drug Name File includes the Knowledge Base Drug Code (KDC) and the Representative KDC Flag as attributes of the DDID.

- When the Representative KDC Flag on a DDID is 1 Exact Match KDC, the KDC in the record can be used to perform clinical screening.
- When the Representative KDC Flag on a DDID is 2 Representative KDC, the KDC is editorially assigned by Wolters Kluwer Clinical Drug Information. For a generic DDID, it is likely to represent only active ingredients. The KDC can be used to perform clinical screening, but if you have a specific NDC-UPC-HRI and want to perform clinical screening to include inactive ingredients specific to that NDC-UPC-HRI, use the KDC in the NDC File.

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- When the Representative KDC Flag on a DDID is 0 Unassigned, the DDID cannot be screened using a KDC. Use the KDC on a specific NDC-UPC-HRI to perform clinical screening.
- If the KDC on an NDC-UPC-HRI is zero-filled, the NDC-UPC-HRI represents a product such as a device, which is inappropriate to screen.

# **Retrieving GPIs for a Dispensable Drug**

The Drug Name File includes the Generic Product Identifier (GPI) and the Representative GPI Flag as attributes of the DDID.

- When the Representative GPI Flag on a DDID is 1 Exact Match GPI, the GPI in the record can be used to perform clinical screening.
- When the Representative GPI Flag on a DDID is 2 Representative GPI, the GPI is editorially assigned by Wolters Kluwer Clinical Drug Information. The GPI can be used to perform clinical screening, but if you have a specific NDC-UPC-HRI and want to perform clinical screening with GPI specific to that NDC-UPC-HRI. To do so:
  - > Retrieve the GPPC for the NDC-UPC-HRI in the NDC File.
  - > Using the GPPC, retrieve the associated GPI in the GPPC File.
- When the Representative GPI Flag on a DDID is 0 Unassigned, the DDID cannot be screened using a GPI. Use the GPI on a specific NDC-UPC-HRI to perform clinical screening.

# Identifying Therapeutic Alternatives Using the TC-GPI Name File

The TC-GPI Name File can be used as a starting point in identifying therapeutic alternatives. This may aid in creating and maintaining a formulary for the purposes of prescribing, defining drug benefit plans, purchasing, and inventory.

The following examples illustrate some of the options you can consider in defining alternatives using the Wolters Kluwer Clinical Drug Information Therapeutic Classification System (TCS) hierarchy. The needs of your end-users will determine whether more specific or more general levels of the GPI hierarchy are more appropriate. Additional data elements in MED-File v2 may be used to further filter the number of results. End-users may wish to limit the drugs by DESI Code, DEA Class Code, TEE Code, packing, route of administration, dosage form, Repackage Code, pricing, inactive status, or other values.

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#### **Identifying DDIDs for Drug Class**

#### Example:

- 1. Using the Drug Class "394000" for HMG CoA Reductase Inhibitors as a wild card input for the GPI field, retrieve all matching records in the Drug Name File.
- 2. Use the TC-GPI Name File to retrieve the TC-GPI Name for each GPI within the records obtained in Step 1.
- 3. Use the Drug Descriptor Identifier (DDID) for each record retrieved in Step 1 to retrieve the drug's description from the Description File. The Concept ID in the Description File is a 10-digit representation of the DDID in the Drug Name File. The Concept Type is 00004. The Country Code is 01 USA.

Alternatively, the DDID Description can be built using the Drug Name, Route of Administration, Dose Form, Strength, and Strength Unit-of-Measure fields in the Drug Name File.

DDID	GPI	TC-GPI Name	DDID Description
047764	39400010100310	Atorvastatin Calcium Tab 10 MG (Base Equiv- alent)	Atorvastatin Calcium Oral Tablet 10 MG
047942	39400030100120	Fluvastatin Sodium Cap 20 MG	Lipitor Oral Tablet 10 MG
033801			Fluvastatin Sodium Oral Capsule 20 MG
028392	39400050000305	Lovastatin Tab 10 MG	Lovastatin Oral Tablet 10 MG
013468			Mevacor Oral Tablet 10 MG
083317	39400060100305	Rosuvastatin Calcium Tab 5 MG	Crestor Oral Tablet 5 MG
030827	39400075000340	Simvastatin Tab 10 MG	Simvastatin Oral Tab- let 40 MG

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#### **Identifying NDCs for Drug Class**

#### Example:

- 1. Using the Drug Class "394000" for HMG CoA Reductase Inhibitors as a wild card input for the GPI field, retrieve all matching records in the GPPC File.
- 2. Using the GPPC for each record retrieved in Step 1 as input to the NDC File, retrieving all matching records.
- 3. Use the TC-GPI Name File to retrieve the TC-GPI Name for each GPI within the records obtained in Step 1.
- 4. Use the Drug Descriptor Identifier (DDID) for each record retrieved in Step 1 to retrieve the drug's description from the Description File. The Concept ID in the Description File is a 10-digit representation of the DDID in the NDC File. The Concept Type is 00004. The Country Code is 01 USA.

GPPC	GPI TC-GPI Name	NDC-UPC-HRI	Description
17603028	39400010100310 Atorvastatin Cal-	00071015540	Lipitor Oral Tablet 10 MG
	cium Tab 10 MG (Base Equivalent)		
17603A22	39400010100310	51138022045	Lipitor Oral Tablet 10 MG
	Atorvastatin Cal- cium Tab 10 MG (Base Equivalent)	54868393404	IVIG
13577070	39400030100120	00078017615	Fluvastatin Sodium Oral Capsule 20 MG
	Fluvastatin Sodium Cap 20 MG		oral capsule 20 Mo
13577041	39400030100120	66105014706	Fluvastatin Sodium
	Fluvastatin Sodium Cap 20 MG	13411011106	Oral Capsule 20 MG

# **Creating Nine-Character GPPCs**

Wolters Kluwer Clinical Drug Information's GPPC enables grouping of drug products with the same packaging criteria for the purpose of making purchasing, inventory, and pricing decisions.

The eight-character GPPC allows grouping of drug products based on their active ingredients, strength, and basic packaging criteria. To enable a specific grouping

Documentation Manual 5-55 Published: 11/11 of drug products, you can incorporate Wolters Kluwer Clinical Drug Information's Modifier Codes to further delineate specific packaging, colors, flavors, and so on.

A nine-character GPPC is created by appending a single character of your choosing to an existing eight-character GPPC from Wolters Kluwer Clinical Drug Information. The single character represents a unique combination of Modifier Codes that defines packaging, product, or trademark information.

A nine-character GPPC can be defined at the NDC, GPPC, GPI, or sub-GPI level.

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# Appendix A: Loading and Updating

# In This Chapter

General Product Unpackaging
Telecommunications Transport
File Loading
File Updating
Data Definition Language Policy
Summary File Contents
Summary File Sample
Summary File Processing
Data Dictionary and Validation/Translation Processing
Validation/Translation Look-ups

# **General Product Unpackaging**

For your first issue, you will receive a full initial database. Subsequent issues can be provided as incremental updates or full replacement databases.

Note

The initial incremental update and full replacement databases are available via File Transfer Protocol (FTP) or can be pulled down via HTTP Web Download.

# **Telecommunications Transport**

For information on Wolters Kluwer Clinical Drug Information's two methods of product delivery, FTP Pull and HTTP Download, see below.

## FTP Pull (Pick-up)

If FTP Pull is your method of deliver choice, Wolters Kluwer Clinical Drug Information will place the product files on our FTP site for pick-up. An e-mail notification will be sent once the file transfer is complete. Contact Customer Support to obtain a login and password for our server if you wish to use this method of delivery. You will then be able to log in to pull the files down to your location after they are delivered.

Note	Wolters Kluwer Clinical Drug Information reserves the right to clean old files
	from customer directories as space is needed. Keep your FTP Pull directory
	reasonably clean and do not attempt to use it as a file archive.

#### **HTTP Download (Web Download)**

HTTP Download is available to all customers as an alternate method of delivery, and as a gateway to our documentation library. This site contains the current total database in addition to the current and two previous incremental updates.

Note	Contact Customer Support for your login and password, and for additional
	instructions on using this download site.

#### **Decompressing Files**

To reduce the size of the attachment files, Wolters Kluwer Clinical Drug Information compresses them before sending them to you. The options for the compression method are ZIP and UNIX Pack.

If you are receiving the files	Wolters Kluwer Clinical Drug Information recommends	Then
Microsoft Windows- based system,	using 7-ZIP if you are unable to use the built-in compression/ decompression functionality that is built into current versions of Microsoft Windows.	we can provide the link to the 7-Zip Web site.
on a UNIX system,	using unpack, unless your system administrator directs otherwise.	you can find many versions of UNIX included with the unpack utility.

#### **ZIP Compression**

Many current versions of Microsoft Windows ™ have built in ZIP file decompression and compression functionality. Consult your operating system documentation for more details. Access the 7-Zip Web site (http://www.7-Zip.org) for the most current version of this software. Instructions for using 7-Zip to extract compressed files are located within the 7-Zip Help information.

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# File Loading

When loading your initial database, extract the data and place it into your system. If you need to replace the information in your system, considerations include:

- making a backup copy
- determining processes for deleting current information
- · loading the data from your initial database

# File Updating

If you receive incremental updates, you must process records in the productspecific files according to their transaction codes. Transaction codes indicate the type of file modification to perform. Valid values include:

Code	Description
Α	Add the record to your system. No duplicate key should exist.
С	The record that has a matching key changed and must be updated in your system. The data from the incremental update replaces the data on your system.
D	Delete the record that has a matching key from your system.

Note	Any file may be empty in the incremental update if no information has
	changed.

# **Updating the Copyright File (MF2COPY)**

The Copyright File is to copyright the Wolters Kluwer Clinical Drug Information product only; therefore, it does not require updating.

#### **Updating the Summary File (MF2SUM)**

The Summary File is supplied in its entirety on Incremental Updates. The Summary File contains information on volume, supplement, and expiration, which you will need to process against. (Refer later in this chapter for more information on Summary File Processing.)

## **Updating the Read Me File (MF2READ)**

The Read Me File is for informational purposes only; therefore, it does not require updating.

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#### **Updating the Data Dictionary File (MF2DICT)**

The Data Dictionary File is supplied in its entirety on Incremental Updates. Any change to this file requires you to change other programming.

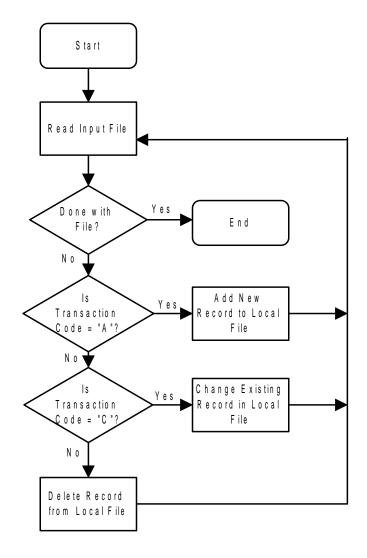
You will receive advanced notification of any changes that affect the definition or length of an existing field or record within a file.

#### **Updating the Validation/Translation File (MF2VAL)**

The Validation/Translation File is supplied in its entirety on Incremental Updates.

The Validation/Translation File may go unchanged from issue to issue. However, new values for a field may be added without advanced notice.

Diagram A.1:Update Using Incremental Updates



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# **Data Definition Language Policy**

Data Definition Language (DDL) files are provided to you as you define the MED-File v2 database structures. MED-File v2 platforms that support DDL are:

- SQL Server
- Oracle

## **Supported DDL Properties**

Below are the DDL properties Wolters Kluwer Clinical Drug Information supports:

Supported DDL Property	Description
Column Naming	The column name and its length adheres to standards that are mutually compatible with all supported database platforms. Column names are 30 characters or less.
Mandatory Fields	Constraints for mandatory columns (not null constraints) are supplied for the appropriate columns for the tables within a module when indicated by the design and supported by the target database.
Primary Key Index Creation	Primary key indexes are provided for primary key columns for the tables within a module when supported by the target database.
Table Creation	The "Create Table" statement is always present for each table delivered within the module. The table name and length adhere to standards mutually compatible with all supported database platforms. Table name lengths are 30 characters or less.

# **Unsupported DDL Properties**

Below are the DDL properties Wolters Kluwer Clinical Drug Information does not support:

Unsupported DDL Property	Description
Data Loading	Coding and scripts to assist the customer while loading and formatting the flat file databases into the structures that have been established by the DDL are not supplied.  Note: Decimal points will not be included in the data.
Foreign Key Creation	Creation of foreign keys is not supported. This allows customers to load their tables in any order they choose.

Unsupported DDL Property	Description
Indexes	Indexes are not directly created; however, primary keys may indirectly result in the creation of an index. This is database-specific and foreign key indexes are not created.
Permission Information	Items such as users, grants, and privileges are not defined in the DDL.
Reserve	There is no reserved space.
Table Sizing Information	Items such as data volume, storage requirements, and number of records are not defined in the DDL.
Transaction Code	Transaction codes, delimiters, and so forth are not supported within the DDL.

## **Testing and Validation**

The DDL files are tested on the following database platforms at Wolters Kluwer Clinical Drug Information:

- SQL Server
- Oracle

#### **Maintenance**

The MED-File v2 DDL files are built according to the documentation contained in this appendix. Updates are in response to enhancements to current MED-File v2 modules and the introduction of new MED-File v2 modules.

# **Script Organization**

The information below is supplied for each of the four file combinations offered for MED-File v2 and their supported databases:

#### Basic

Script Name	Description	
mf2_oracle_basic_CreateTable.sql	This script creates the tables.	
mf2_oracle_basic_Constraint.sql	This script creates the Primary key constraints on the table.	
mf2_mssql_basic_CreateTable.sql	This script creates the tables.	
mf2_mssql_basic_Constraint.sql	This script creates the Primary key constraints on the table.	

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#### Clinical

Script Name	Description	
mf2_oracle_clinical_CreateTable.sql	This script creates the tables.	
mf2_oracle_clinical_Constraint.sql	This script creates the Primary key constraints on the table.	
mf2_mssql_clinical_CreateTable.sql	This script creates the tables.	
mf2_mssql_clinical_Constraint.sql	This script creates the Primary key constraints on the table.	

#### Complete

Script Name	Description	
mf2_oracle_complete_CreateTable.sql	This script creates the tables.	
mf2_oracle_complete_Constraint.sql	This script creates the Primary key constraints on the table.	
mf2_mssql_complete_CreateTable.sql	This script creates the tables.	
mf2_mssql_complete_Constraint.sql	This script creates the Primary key constraints on the table.	

#### Pricing

Script Name	Description	
mf2_oracle_pricing_CreateTable.sql	This script creates the tables.	
mf2_oracle_pricing_Constraint.sql	This script creates the Primary key constraints on the table.	
mf2_mssql_pricing_CreateTable.sql	This script creates the tables.	
mf2_mssql_pricing_Constraint.sql	This script creates the Primary key constraints on the table.	

# **Naming Standard**

For the .sql file type, the naming standard is Structured Query Language.

Note	The data delivery media will always contain either a Total Database or an
	Incremental Update file.

# **Mapping Tables**

The table below details the mappings from the file name to the table name.

File Name	Table Name
MF2COPY (Copyright File)	MF2COPY
MF2READ (ReadMe File)	MF2READ
MF2DICT (Data Dictionary File)	MF2DICT
MF2VAL (Validation/Translation File)	MF2VAL
MF2SUM (Summary File)	MF2SUM
MF2NAME (Drug Name File)	MF2NAME
MF2TCGPI (TC-GPI Name File)	MF2TCGPI
MF2NDC (NDC File)	MF2NDC
MF2LAB (Labeler File)	MF2LAB
MF2GPPC (GPPC File)	MF2GPPC
MF2ERR (Error Correct File)	MF2ERR
MF2GPR (GPPC Price File)	MF2GPR
MF2PRC (NDC Price File)	MF2PRC
MF2MOD (Modifier File)	MF2MOD
MF2NDCM (NDC Modifier File)	MF2NDCM
MF2DRGNM (SDI Drug Name File)	MF2DRGNM
MF2RTDRG (Routed Drug File)	MF2RTDRG
MF2DFDRG (Drug-Dose Form File)	MF2DFDRG
MF2RTDF (Routed Dose Form File)	MF2RTDF
MF2DRG (Dispensable Drug File)	MF2DRG
MF2DESC (Description File)	MF2DESC
MF2RTE (Route File)	MF2RTE
MF2FRM (Dose Form File)	MF2FRM
MF2STUOM (Strength-Strength Unit of Measure File)	MF2STUOM
MF2SET (Drug Concept ID to Ingredient Set ID File)	MF2SET
MF2INGS (Ingredient Set ID to Ingredient ID File)	MF2INGS
MF2STR (Ingredient ID to Drug-Strength File)	MF2STR
MF2IDRG (Drug ID File)	MF2IDRG
MF2SEC (Secondary Alternate ID File)	MF2SEC
MF2RNM (Reference Name File)	MF2RNM

Note

Not all customers will receive all files listed in the table above. The files you receive are based on the layout of the MED-File v2 that you have licensed.

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# **Summary File Contents**

The Summary File contains the Issue Date, Expiration Date, and File Mode for a Total Database and Incremental Update. This information can be used to ensure that issues are loaded in the correct order (Issue Checking) and that data being used have not expired (Expiration Checking).

#### **Summary File Record Types**

The Record Type indicates what type of data is contained within each Summary File record. The possible values for Record Type are:

Record Type	Description
CCR	Copyright Statement
CDC	Create Date
CDE	Expiration Date
CDI	Issue Date
CDJ	Grace Message Date
CDK	Kill Date
CFM	File Mode
CFT	File Type
CPN	Product Name
CPV	Product Version (Issue)
CVL	Volume Number and Supplement Number
LCC	Locality Information - Country Code
LLC	Locality Information - Language Code
TOC	Table of Contents

## **Sequence Number**

The Sequence Number allows ease of sorting comments and data within a Record Type. No meaning is given to these values, and they may increment by any number (such as 1s, 5s, or 10s). This increment may not be consistent within or among Record Types. (For examples of Sequence Number, refer to "Summary File Sample" later in this chapter.)

#### **Comment Marker**

The Comment Marker helps when viewing the Summary File and enhances readability when the Summary File is printed. When the Comment Marker contains an asterisk (\*), the information in the data portion of the record describes the data following. When the Comment Marker contains a blank, actual data is in the remaining data portion of the record. (For examples of Comment Marker, refer to "Summary File Sample" later in this chapter.)

#### **Data**

Data following a Comment Marker containing an asterisk (\*) is a text description of the Record Type. Data following a blank Comment Marker is the actual value for that Record Type. (For examples of data, refer to "Summary File Sample" below.)

# **Summary File Sample**

```
CCR 010 Copyright 2011 Clinical Drug Information, LLC
CDC 010 * Create Date
CDC 020 20111027
CDE 010 * Expiration Date
CDE 020 20111109
CDI 010 * Issue Date
        20111102
CDI 020
CDJ 010 * Grace Message Date
CDJ 020
        20111109
CDK 010 * Kill Date
CDK 020
        20111209
CFM 010 * Product File Mode (P-Production, T-Test)
CFM 020
CFT 010 * Product File Type (T-Total, U-Update)
CFT 020 T
CFF 010 * Product File Format (F-Fixed, D-Delimited)
CFF 020 F
CPN 010 * Product Name
CPN 020
        MEDI-SPAN ELECTRONIC DRUG FILE (TM) V2
CPV 010 * Product Version (Issue)
CPV 020 * YY.Q.F.NNN Year, Quarter Number, Frequency, Publication Number
CPV 030 * Q = 1,2,3,4, F = Blank (Qtrly), 1 Monthly,
CPV 040 *
            2 Semi-Monthly,
CPV 050 * 3 Weekly, 4 Daily
CPV 060 11.4.3.005
CVL 010 *
CVL 015 * Volume Number
CVL 020 * Vol Supplement
CVL 022 * No. No.
CVL 025 * ---- --
CVL 030
        00044 00
LCC 010 *
LCC 020 * Country Code and Country
LCC 030 * (01 USA, 02 Canada, 03 Mexico)
LCC 040 * CC Country
LCC 050 * -- -----
LCC 060 01 USA
LLC 010 *
LLC 020 * Language Code and Language
LLC 030 * (01 English, 02 Spanish)
LLC 040 * LC Language
LLC 050 * -- -----
        01 English
LLC 060
TOC 010 *
TOC 020 * Table of Contents
TOC 030 * Pt Fil
TOC 040 * ## Num File Name Rec Cnt
```

TOC	050	*				
TOC	110		01	010	MF2COPY	0000001
TOC	120		01	020	MF2SUM	0000080
TOC	130		01	030	MF2READ	0000002
TOC	140		01	040	MF2DICT	0000272
TOC	150		01	050	MF2VAL	0000752
TOC	160		01	060	MF2NAME	0048152
TOC	170		01	070	MF2TCGPI	0034231
TOC	180		01	080	MF2NDC	0168859
TOC	190		01	090	MF2LAB	0001547
TOC	200		01	100	MF2GPPC	0055124
TOC	210		01	110	MF2ERR	0000108
TOC	220		01	120	MF2GPR	0014192
TOC	230		01	130	MF2PRC	0337090
TOC	240		01	140	MF2MOD	0004118
TOC	250		01	150	MF2NDCM	0171829
TOC	260		01	160	MF2DRGNM	0047604
TOC	270		01	170	MF2RTDRG	0049766
TOC	280		01	180	MF2DFDRG	0054487
TOC	290		01	190	MF2RTDF	0055157
TOC	300		01	200	MF2DRG	0071041
TOC	310		01	210	MF2DESC	0338994
TOC	320		01	220	MF2RTE	0000035
TOC	330		01	230	MF2FRM	0000093
TOC	340		01	240	MF2STUOM	0006493
TOC	350		01	250	MF2SET	0239900
TOC	360		01	260	MF2INGS	0126896
TOC	370		01	270	MF2STR	0028732
TOC	380		01	280	MF2IDRG	0004529
TOC	390		01	290	MF2SEC	0007628

# **Summary File Processing**

#### **Issue Checking Processing**

The Summary Record Types of CFT (Product File Type) and CVL (Product Volume Number) allow you to ensure that once the initial load (Total Database) is complete, product updates are used and processed in order.

The Product File Type should be "T" for the Total Database of production data only. All subsequent products received should have a Product File Type of "U".

When you receive your initial load, record the Volume Number of that product. Each monthly or quarterly product you receive from that point forward should have a volume number incremented by one from the last Volume Number processed.

In between monthly or quarterly issue dates, you may receive a supplemental issue of the product with data that should not wait until the next issue date to be distributed. These products will have the same Volume Number as last product issue processed, but the supplement number should be incremented by

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one for each supplement between normal issues. (Refer to Supplement Processing later in this chapter for more information.)

Note	Loading data out of sequence for Incremental Updates will corrupt
	the database and yield incorrect results.

# Note If you receive a product with a Volume Number incremented by more than one, you have missed an issue. If you receive an issue where the volume number is the same as the last one processed and the supplement number is zero, you have received a duplicate issue or are trying to reload an issue you have already applied. Contact your Wolters Kluwer Clinical Drug Information Customer Support Representative immediately in the case of a missing issue or the receipt of a duplicate issue.

#### **Expiration Checking**

Expiration Checking is required for the implementation of the database. The Expiration Date is specified in the CDE Record of the Summary File. The Kill Date appears in the CDK Record.

Note	The database must not be accessible by the end-user after the Kill Date and
	should remain disabled until the next issue is applied. If a subscription has
	been canceled, the database must be removed from the end-user's system.

You can use the Expiration Date to warn end-users that data has expired indicating a new issue of the product should be applied. This warning can continue to be output throughout the grace period between the Expiration Date and the Kill Date. Once the Kill Date is reached, the database must be updated or disabled.

#### **Checking for Product Expiration**

The following general logic explains how to check for expiration of a product:

- 1. Check the System Date as the system is initiated each day.
- 2. If the System Date is later than the Expiration Date, but earlier than the Kill Date, provide the end-user with a warning. We recommend that you identify the number of days remaining to update the product (Kill Date minus the System Date).
- 3. If the System Date is past the Kill Date, inform the end-user that the system has been disabled and is unavailable for use until the database is updated.

A-12 MED-File v2 Published: 11/11 Revised: 01/18 Delete any files that are specific to the expired issue if your subscription has been canceled. Otherwise, keep the system disabled until you receive and apply the new issues.

#### **Copyright and Issue Display**

It is required that the Copyright Statement and Version (Issue) Number be listed on all printed reports generated using data from MED-File v2. To do this, select the Copyright Statement from Record Type CCR and the version from Record Type CPV.

Example:

Copyright 2011 Clinical Drug Information, LLC Issue 08.1.1.002

### **Supplement Processing**

When issues are provided as mid-cycle supplements, it is important to understand what you are receiving.

Each supplement contains the entire normal issue's update transactions plus additional ones that could not wait until the next issue of the product. The next issue will contain all changes in the cycle including those that already were distributed in supplements.

Additions, changes, and deletions found in the regular issue may have already been applied if supplements are received and applied in between regularly scheduled issues. Make sure that integrity checks on Transaction Codes are not in effect during the application of the next issue following a supplement; such as an addition ("A" Transaction Code) of something already on file is acceptable if an optional supplemental update has been applied.

# **Data Dictionary and Validation/Translation Processing**

#### **Automated Database Import**

The product-specific files included in MED-File v2 are relational in nature and can be loaded directly into corresponding tables in a relational database. To set up the import of product files:

1. Cross-match the initial letter of the Field Identifier field in the Data Dictionary File to the file it represents, including the Data Dictionary and Validation/Translation Files, since you will need to reference their

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- information in normal processing.
- 2. Generate a script or code to create database tables based on the information in the Data Dictionary File. There will be a table "create" for each unique starting letter. Substitute the meaningful names described in step 1 as the actual table names. Each field definition should have the meaningful name from the Field Description, a type based on the Field Type, and the size indicated in the Field Length.

**Note** To avoid confusion and minimize changes if the layouts of the product files change, do not use the Field Identifier values as field names.

- 3. Prepare for the import process per file by defining the starting location of each field in that file as the number immediately following the initial letter of each Field Identifier field. If the Implied Decimal Flag is "Y" for a particular field, format the input of that field to have the number of decimal places as specified in the Decimal Places field.
- 4. Execute each import to populate each database table.

**Note** Once the initial database tables are created and populated, you must set up a separate application to read incremental updates and change the database contents based on Transaction Codes.

# Validation/Translation Look-ups

Much of the MED-File v2 information is encoded; therefore, numbers represent more meaningful, longer values. This saves room in the transfer files and your internal storage. What this requires is that you translate the encoded value to the more meaningful value at the time you output information to your end-users.

To do this processing, you need to do some initial setup. Set up a cross-reference table of the logical name of a field within a file to its corresponding Field Identifier value in the Data Dictionary File. Make sure you are tracking the Field Validation Flag and Field Abbreviation Flag per Field Identifier value.

You can then set up a standard routine prior to any user output to look up the logical field name and see if it has corresponding values (based on the Field Validation Flag and Field Abbreviation Flag). If a flag is set, look up the corresponding Field Identification value in the Validation/Translation File and obtain the Value Description or Value Abbreviation based on the encoded field value you have to output. If both flags are set, determine which is more appropriate for your application and use that corresponding value.

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# Appendix B: Record Layout Diagrams

## In This Appendix

Introduction
Record Layouts For MED-File v2

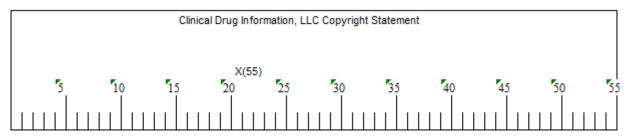
#### Introduction

This appendix contains the MED-File v2 record layouts. The shaded fields represent the unique key into the file.

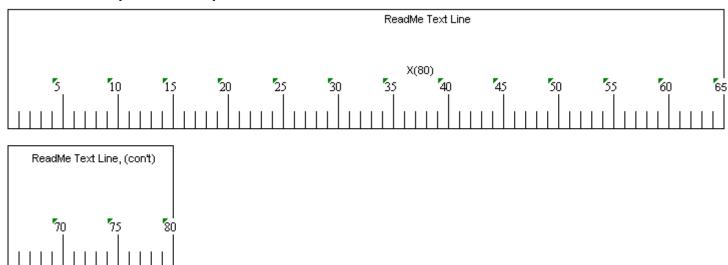
For more information about record layouts, see Chapter 4, "MED-File v2 Data Elements".

# **Record Layouts For MED-File v2**

#### **Copyright File (MF2COPY)**

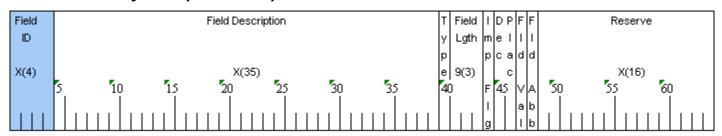


#### ReadMe File (MF2READ)

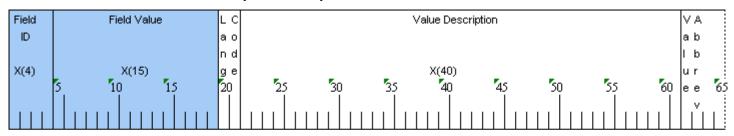


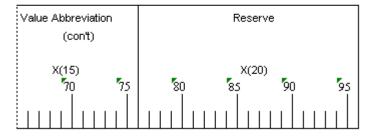
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#### **Data Dictionary File (MF2DICT)**

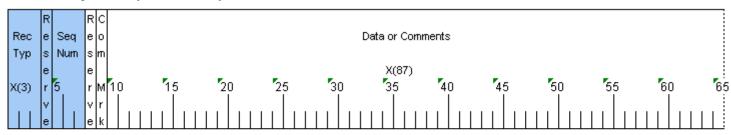


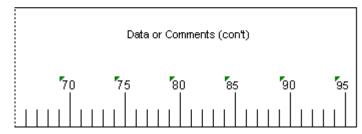
#### **Validation/Translation File (MF2VAL)**





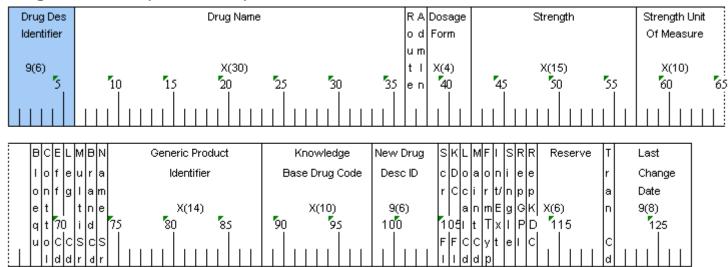
## **Summary File (MF2SUM)**



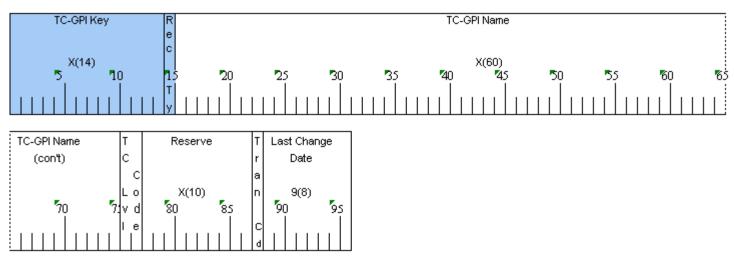


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#### **Drug Name File (MF2NAME)**



#### TC-GPI Name File (MF2TCGPI)



# NDC File (MF2NDC)

NDC-UPC-HRI	Drug	T CDD	R Generic	Old NDC-UP	C-HRI	New NDC-UPC-HRI	RIT	Knowledge Base
	Descriptor	E OEE	x Product				e D h	Drug Code
	Identifier	E d A S	OPackaging Code	;			p # r	
X(11)	9(6)	e   I	T X(8)	X(11)		X(11)	k d	X(10)
5 10	15	20	c 25	30 35	40	45 50	55 و	60 6
	.	_  c c	[i] [	.     .		.		
			n	<u>                                     </u>			aaa	
KMS Labeler M N I I C	R PHDD	RSL	Old Effective	New Effective	N N		Τ	Last Change
D Identifier uatnI	e  P F i I	x t m	Date	Date	× N× N	Reserve-2	r	Date
C   I m e n i	s 1   G   P   s   r	r t 0			t Dt D		a	
9(5) temorn	e    G	Rg o	YYYYMMDD	YYYYMMDD	c  c	X(13)	-	- 1-7
F  70       i	r I 8(UR	a Dd	90	95 100	s L	110 115	120	125
	v_  n 1  n n	n c s e			m N g N			
lal I I I I I I I I I I I I I I I I I I	lel lalnitik	lk lolt l			m   m			1

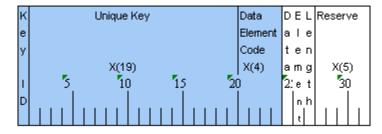
# Labeler File (MF2LAB)

Medi-Span	Manufacturer's (Lai	oeler) Name	Manufacturer	L	Reserve	Т	Last Change
Labeler			Abbreviated	а		r	Date
Identifier			Name	b		a	
9(5)	X(30)		X(10)	ı	X(9)		9(8)
5	10 15 20	25 30 35	5 40 45	5	50 55	5	60
				т		d	
				l <sub>y</sub> l		ᅦᅦ	

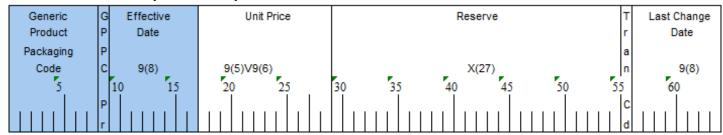
#### **GPPC File (MF2GPPC)**

	Generic Product	Package	ΡS	Package	υ	РD	Generic Product	Reserve	Т	Last Change
	Packaging Code	Size	аz	Quantity	þ	ае	Identifier		r	Date
			С		υ	сs			a	
	X(8)	9(6)V9(3)	k U	9(5)	υ	kс		X(14)	n	9(8)
١	5	10 15	a 0	20	2.	5	30 35 40	45 50 55	5	60
1			g M		c	c			Id	
١			e	$  \   \   \   \  $	d	d			a	

#### **Error Correct File (MF2ERR)**



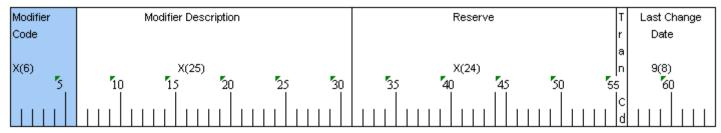
#### **GPPC Price File (MF2GPR)**



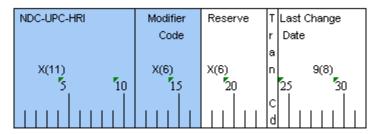
#### NDC Price File (MF2PRC)



#### **Modifier File (MF2MOD)**



#### NDC Modifier File (MF2NDCM)

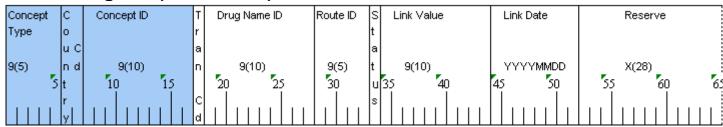


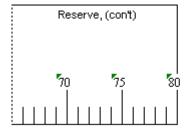
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#### **SDI Drug Name File (MF2DRGNM)**

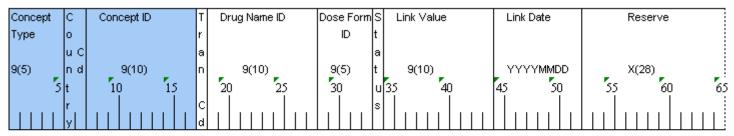
Concept	С	Concept ID	Т	N	s	Link Value	Link Date	Reserve
Туре	0		r	a	t			
	u C		a	m	а			
1 1 1	n d	9(10)	n	e	t	9(10)	YYYYMMDD	X(10)
5	t	10 15			u	25 3	o <b>3</b> 5	40 45
	r		þ	Т	s			.
	уL		d	y				

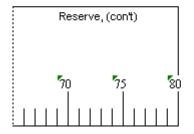
#### **Routed Drug File (MF2RTDRG)**



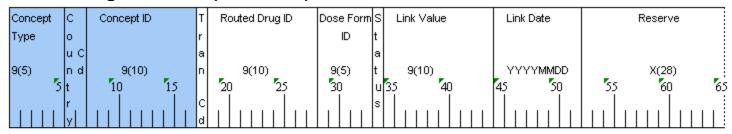


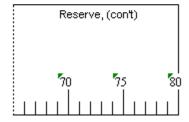
#### **Drug-Dose Form File (MF2DFDRG)**





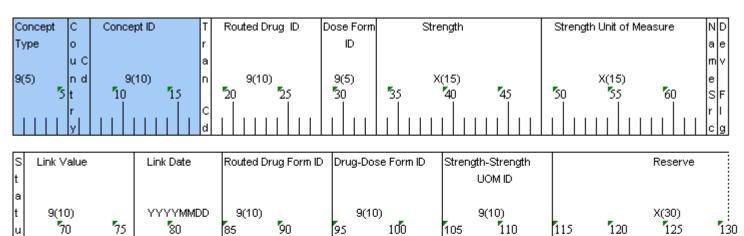
#### **Routed Drug Form File (MF2RTDF)**

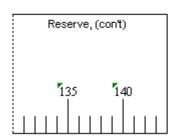




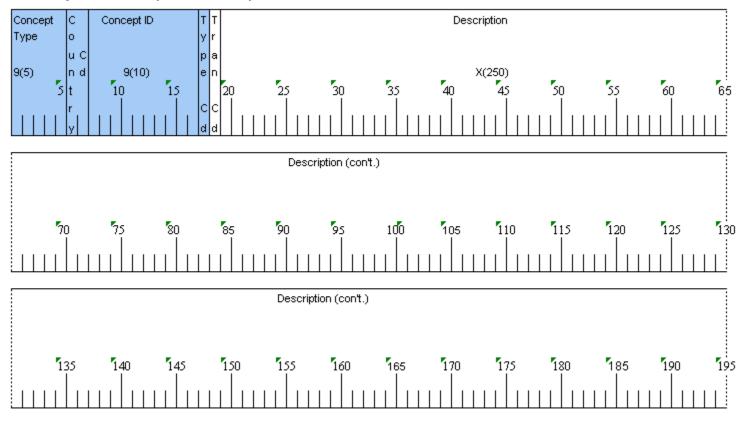
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#### **Dispensable Drug File (MF2DRG)**



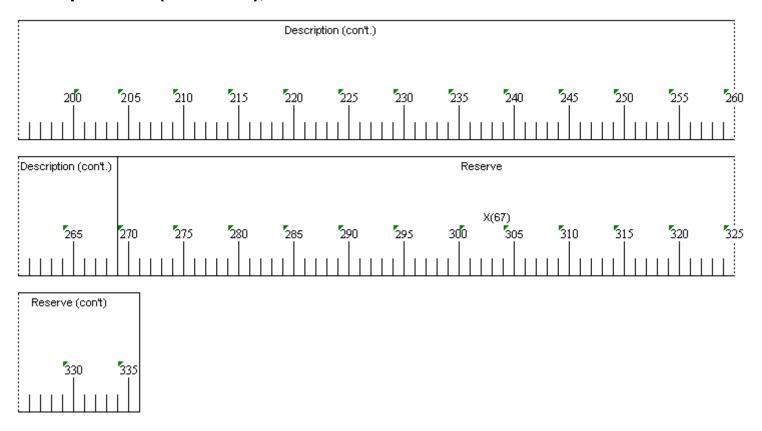


#### **Description File (MF2DESC)**



continued on next page

#### Description File (MF2DESC), continued



# Route File (MF2RTE)

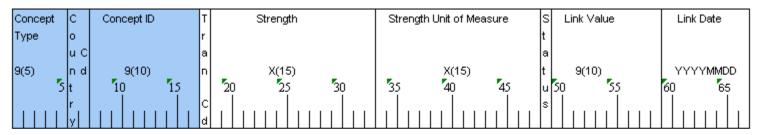
Concept	С	Concept ID	Т	S	Link Value	Link Date	Reserve
Туре	0		r	t			
	u C		a	а			
9(5)	n d	9(10)	n	t	9(10)	YYYYMMDD	X(11)
5	t	10 15	ı	u	20 25	30 35	40 45
	r		c	s			
	ly L		d				

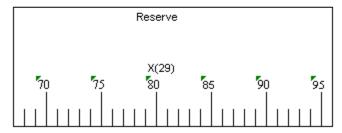
# Dose Form File (MF2FRM)

Concept	С	Concept ID	Т	s	Link Value	Link Date	Reserve
Туре	0		r	t			
	u C		а	а			
9(5)	n d	9(10)	n	t	9(10)	YYYYMMDD	X(11)
5	t	10 15	ı	u	20 25	30 35	40 45
	r		c	s			
	у		d				

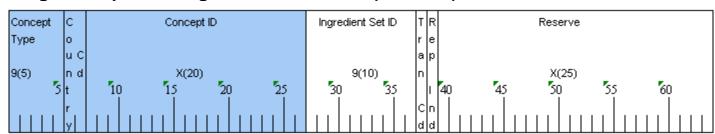
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#### **Strength-Strength Unit of Measure File (MF2STUOM)**

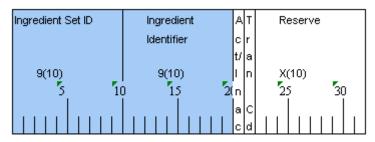




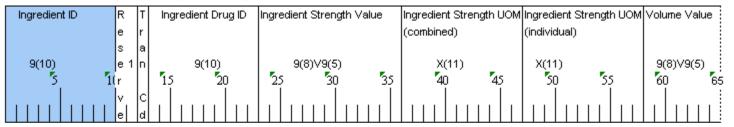
## **Drug Concept ID to Ingredient Set ID File (MF2SET)**

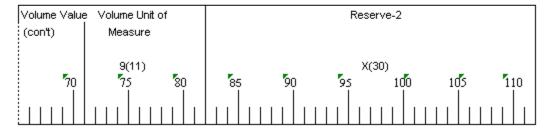


#### Ingredient Set ID to Ingredient Set ID File (MF2INGS)



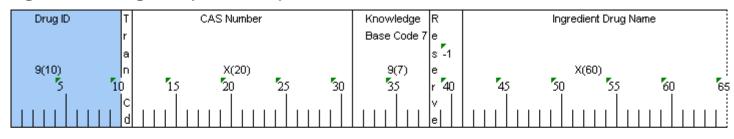
#### **Ingredient ID to Drug-Strength File (MF2STR)**

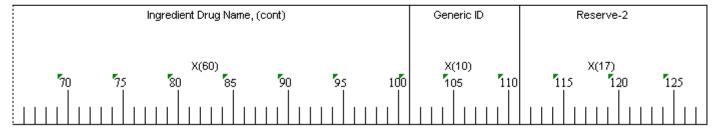




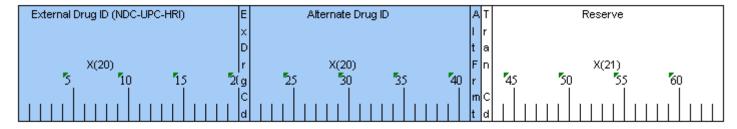
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#### **Ingredient Drug File (MF2IDRG)**

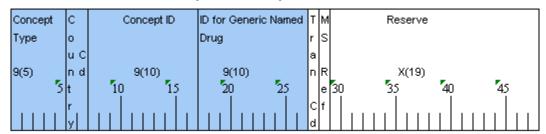




#### **Secondary Alternate ID File (MF2SEC)**



## Reference Name File (MF2RNM)



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# **Appendix C: GPI Name Abbreviations**

#### **GPI Abbreviation List**

Below is the list of GPI names and abbreviations.

**Note** This list includes, but is not limited to the following abbreviations.

Abbreviation	Full Name
Α	Vitamin A
Ace	Acetate
Alk	Alkaloids
Alum or Al	Aluminum
AmCI	Ammonium Chloride
Amyl	Amylase
APAP	Acetaminophen
APC	Aspirin, Phenacetin, and Caffeine
ASA	Aspirin
Azo	Phenazopyridine
B Complex	Vitamin B1, B2, B3, B5, B6, and B12
B1	Thiamine HCI
B2	Riboflavin
B3	Niacin
B5	Calcium Pantothenate or Pantothenic Acid
B6	Pyridoxine HCI
B12	Cyanocobalamin
BAC	Benzalkonium Chloride
Bell	Belladonna
Bella Alk	Belladonna Alkaloids
Benzo	Benzocaine
Bicarb	Bicarbonate
Biphos	Biphosphate
Bis	Bismuth
BPM	Brompheniramine Maleate
Bromodiphen	Bromodiphenhydramine HCI
Bromphen	Brompheniramine Maleate

Abbreviation	Full Name
Butabarb	Butabarbital
С	Ascorbic Acid
Ca	Calcium
Caff	Caffeine
Cal	Calcium
Carb	Carbonate
Carbeta	Carbetapentane Citrate
Cellu	Cellulase
Chlorphen	Chlorpheniramine Maleate
CI	Chloride
COD	Codeine
Conj	Conjugated
CPM	Chlorpheniramine Maleate
Cr	Chromium
Cu	Copper
D	Vitamin D
D5W	Dextrose 5% in Water
DES	Diethylstilbestrol
DHA	Docosahexaenoic Acid
DM	Dextromethorphan HBr
Doxyl	Doxylamine Succinate
DPH	Diphenhydramine HCI
DSS	Docusate Sodium
E	Vitamin E
EPA	Eicosapentaenoic Acid
Ephed	Ephedrine HCI
Eth	Ethinyl
FA	Folic Acid
Fe	Iron
Fe Asp	Ferrous Aspartate
Fe Asparto Glyc	Ferrous Asparto Glycinate
Fe Cbnyl	Iron Carbonly
Fe Fum	Ferrous Fumarate
Fe Glyc	Ferrous Glycinate
Fe Polysacch Cmplx	Polysaccharide Iron Complex
Fe Prot Succ	Iron Protein Succinylate
GG	Guaifenesin
Glyc	Glycinate
Guaiacol	Guaiacolsulfonate
HBr	Hydrobromide
HC	Hydrocortisone
HCI	Hydrochloride

Abbreviation	Full Name
HCTZ	Hydrochlorothiazide
Hydrocod	Hydrocodone
Hydrox	Hydroxide
Hyosc	Hyoscyamine
I	Iodine
IF	Intrinsic Factor
IFC	Intrinsic Factor
K	Potassium
KCI	Potassium Chloride
KI	Potassium Iodide
Lac	Lactate
Lip	Lipase
Mag	Magnesium
Meth Blue	Bethylene Blue
Methamphet	Methamphetamine HCI
Methenamine Mand	Methenamine Mandelate
Methyltest	MethItestosterone
Mg	Magnesium
Min	Minerals
Mn	Manganese
Multivit	Multivitamins
Na	Sodium
NaCl	Sodium Chloride
PB	Phenobarbital
PE	Phenylephrine HCI
PEG	Polyethylene Glycol
Pentobarb	Pentobarbital
PETN	Pentaerythritol Tetranitrate
PG	Paregoric
Phenid	Phenindamine Tartrate
Phenir	Pheniramine Maleate
Phenyl Sal	Phenyl Salicylate
Phenyleph	Phenylephrine HCI
Phenylprop	Phenylpropanolamine HCI
Phenyltolox	Phenyltoloxamine
Phos	Phosphate
Pot	Potassium
Pot Guaiacol	Potassium Guiacolsulfonate
PPA	Phenylpropanolamine HCI
Prop	Propionate
Propoxyphene-N	Propoxyphene Napsylate
PSE	Pseudoephedrine

Abbreviation	Full Name				
Pseudoeph	Pseudoephedrine				
Ptolox	Phenyltoloxamine Citrate				
Pyril	Pyrilamine Maleate				
Sal	Salicylate				
Salamide	Salicylamide				
Se	Selenium				
Simeth	Simethicone				
Sod	Sodium				
Subgal	Subgallate				
Subsal	Subsalicylate				
Tan	Tannate				
Theo	Theophylline				
Trisil	Trisilicate				
Val	Valerate				
w/o	without				
Zn	Zinc				
Zn Ph	Zinc Phenol				

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# Appendix D: Dosage Form Codes

# **In This Appendix**

Dosage Form Current Values

#### **Dosage Form Current Values**

The Dosage Form indicates the form (solid, liquid, or gas) in which the drug product is dispensed. Dosage Forms are standard throughout every Drug Group.

For more information, see Dosage Form in Chapter 2: Editorial Policies.

Note

Alpha-numeric dosage form values are included in the table below. These values will be phased in over time in new alpha-numeric GPIs during planned GPI change cycles. Consequently, the alpha-numeric dosage forms may not be all-inclusive of their products until the appropriate GPI changes can be made.

#### Examples include:

Dosage Form Description	Code	Abbreviation	C6	Comments
Aerosol	AERO	Aerosol	32	An ingredient that is atomized into a fine mist (form unspecified); includes products under pressure and pump sprays.†
Aerosol, Breath Activated	AERB	Aero Breath Act	81	An unspecified or liquid aerosol (see aerosol) which is activated to induce atomization of the dose by patient inhalation.
Aerosol, Powder	AERP	Aerosol Powder	33	A powder-form aerosol (see aerosol) that is atomized into a fine mist.

Dosage Form	Code	Abbreviation	C6	Comments
Description				
Aerosol Powder, Breath Activated	AEPB	Aero Pow Br Act	80	A powder-form aerosol (see aerosol) which is activated to induce atomization of the dose by patient inhalation.
Aerosol, Solution	AERS	Aerosol Soln	34	A solution-form aerosol (see aerosol) that is atomized into a fine mist.
Auto-injector	AUIJ	Auto-injector	D4	A medication in an Auto- injector. An Auto-injector is a device that uses a spring-loaded mechanism to drive a hypodermic needle into a patient to a predetermined depth below the skin surface. Drug form unknown.
Auto-injector Kit	AJKT	Auto-inj Kit	F5	A medication in an Auto- injector (see Auto- injector) that is available as a kit.
Bar	BAR	Bar	35	A solid dosage form usually in the form of cake or a rectangle (may have a solid or semi-solid interior).
Beads	BEAD	Beads	36	A small, solid dosage form in the shape of a small ball.
Capsule	CAPS	Capsule	01	A solid dosage form in which the ingredients are enclosed within either a hard or soft soluble container or "shell". The shells are usually formed from gelatin, but may be made of other suitable substances.
Capsule Abuse- Deterrent	CAPA	Cap Abuse Deter	A1	Capsule (see capsule dose form) with abusedeterrent properties or labeling that use physical or chemical barriers or delivery systems

Dosage Form	Code	Abbreviation	C6	Comments
Description				
Capsule Chewable	CPCW	Chew Cap	F9	A capsule that is intended to be chewed and then swallowed. Includes chewable capsules that may be either swallowed whole or chewed, based on patient preference and tolerance, as long as the capsule is designed with an option to be chewed prior to swallowing.
Capsule Delayed Release	CPDR	Capsule DR	65	A capsule (see capsule) which is designed to delay the release of ingredients until the capsule has passed into a specific region of the gastrointestinal tract.
Capsule Delayed Release Particles	CPEP	Capsule DR Part	67	A capsule (see capsule) in which the ingredient particles (beads, pellets, particles, etc.) enclosed in a capsule are enteric coated.
Capsule Delayed Release Sprinkle	CSDR	Cap DR Sprinkle	H1	A capsule (see capsule) which is designed to delay the release of ingredients until the capsule or its contents has passed into a specific region of the gastrointestinal tract. The capsule may be pulled apart and the contents "sprinkled" on food for oral administration.
Capsule Delayed Release Therapy Pack	CDPK	CPDR Ther Pack	B3	Therapy pack with only capsule delayed release dose form.

Dosage Form	Code	Abbreviation	C6	Comments
Description				
Capsule ER 12 Hour Abuse- Deterrent	C12A	Cap 12HR Deter	A3	Capsule Extended Release which is designed to release ingredients at a controlled rate (see capsule extended release 12 hour) with abusedeterrent properties or labeling that use physical or chemical barriers or delivery systems. The dose form is designed to facilitate a 12 hour dosing frequency (interval).
Capsule ER 24 Hour Abuse- Deterrent	C24A	Cap 24HR Deter	A4	Capsule Extended Release which is designed to release ingredients at a controlled rate (see capsule extended release 24 hour) with abusedeterrent properties or labeling that use physical or chemical barriers or delivery systems. The dose form is designed to facilitate a 24 hour dosing frequency (interval).
Capsule ER 12 Hour Sprinkle	CS12	CP12 Sprinkle	F2	A capsule extended release which is designed to release ingredients at a controlled rate. The capsule may be pulled apart and the contents "sprinkled" on food for oral administration. The dose form is designed to facilitate a 12 hour dosing frequency (interval).

Dosage Form	Code	Abbreviation	C6	Comments
Description				
Capsule ER 24 Hour Sprinkle	CS24	CP24 Sprinkle	F3	A capsule extended release which is designed to release ingredients at a controlled rate. The capsule may be pulled apart and the contents "sprinkled" on food for oral administration. The dose form is designed to facilitate a 24 hour dosing frequency (interval).
Capsule ER 12 Hour Therapy Pack	C2PK	CP12 Ther Pack	B5	Therapy pack with only capsule release 12 hour dose form.
Capsule ER 24 Hour Therapy Pack	C4PK	CP24 Ther Pack	B6	Therapy pack with only capsule extended release 24 hour dose form.
Capsule Extended Release <sup>*</sup>	CPCR	Capsule ER	02	A capsule (see capsule) which releases any part of a dose over an extended period of time due to the release characteristics of the capsule design. The release rate allows at least a reduction in dosing frequency (various unspecified intervals).
Capsule Extended Release 12 Hour	CP12	Capsule ER 12HR	69	A capsule (see capsule) which is designed to release ingredients at a controlled rate. The dose form is designed to facilitate a 12 hour dosing frequency (interval).
Capsule Extended Release 24 Hour	CP24	Capsule ER 24HR	70	A capsule (see capsule) which is designed to release ingredients at a controlled rate. The dose form is designed to facilitate a 24 hour dosing frequency (interval).

Dosage Form	Code	Abbreviation	C6	Comments
Description				
Capsule Extended Release Abuse- Deterrent	CPEA	Cap ER Deter	A2	Capsule Extended Release (see capsule extended release) which releases any part of a dose over an extended period of time due to the release characteristics of the capsule design with abuse-deterrent properties or labeling that use physical or chemical barriers or delivery systems
Capsule Extended Release Sprinkle	CSER	Cap ER Sprinkle	F1	A capsule extended release which is designed to release ingredients at a controlled rate. The capsule may be pulled apart and the contents "sprinkled" on food for oral administration.
Capsule Extended Release Therapy Pack	CEPK	CPER Ther Pack	B4	Therapy pack with only capsule extended release dose form.
Capsule Sprinkle	CPSP	Cap Sprinkle	68	A capsule (see capsule), which may be pulled a part and the contents "sprinkled" on food for oral administration.
Capsule Therapy Pack	CPPK	Cap Ther Pack	B2	Therapy pack with only capsule dose form.
Cartridge	CART	Cartridge	E1	Medication in a cartridge with or without a needle. Drug form unknown.
Cartridge Kit	CTKT	Cartridge Kit	F7	Medication in a cartridge with our without a needle available as a kit.
Concentrate	CONC	Concentrate	13	A liquid dose form that is present in a high concentration that may require dilution prior to administration.†

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Dosage Form	Code	Abbreviation	C6	Comments
Description Description	Code	Abbieviation	CO	Comments
Cream	CREA	Cream	37	A semi-solid dosage form containing one or more ingredients that are dissolved or dispersed in a suitable base. Most commonly oil-in-water emulsions or aqueous microcrystalline dispersions of long chain fatty acids or alcohols that are washable.
Crystals	CRYS	Crystals	38	An angular solid of crystalline form. †
Device	DEVI	Device	62	A non-drug item designed for a specific purpose.
Diagnostic Test	TEST	Test	60	A chemical, biological or other test that may be used in conjunction with other diagnostic evidence to formulate a diagnosis, monitor the health of a patient, or evaluate the status of a patient's disease state.
Diaphragm	DPRH	Diaphragm	54	A flexible ring covered with a dome-shaped sheet of elastic material.
Disk	DISK	Disk	98	A circular, plate-like structure.
Elixir	ELIX	Elixir	10	A clear, sweetened, hydroalcoholic liquid that is commonly used as a vehicle for ingredients intended for oral use <sup>†</sup>
Emulsion	EMUL	Emulsion	16	A two-phase system in which one liquid is dispersed throughout another liquid in the form of small droplets.†
Enema	ENEM	Enema	51	A liquid preparation intended for rectal instillation (or a solute that may be diluted) for therapeutic, diagnostic or nutritive purposes.

Dosage Form	Code	Abbreviation	C6	Comments
Description				
Exhaler	EXHA	Exhaler	G3	A breath activated exhalation drug-device combination that deposits drugs high and deep in the nose where the drug form is unknown.
Exhaler Liquid	EXHL	Exhaler Liq	G5	A breath activated exhalation drug-device combination that deposits drugs high and deep in the nose where the drug form is a liquid.
Exhaler Powder	EXHP	Exhaler Powd	G4	A breath activated exhalation drug-device combination that deposits drugs high and deep in the nose where the drug form is a powder.
Exhaler Solution	EXHS	Exhaler Soln	G6	A breath activated exhalation drug-device combination that deposits drugs high and deep in the nose where the drug form is a solution.
Exhaler Suspension	EXHU	Exhaler Susp	G7	A breath activated exhalation drug-device combination that deposits drugs high and deep in the nose where the drug form is a suspension.
Film	FILM	Film	82	A thin, pliable layer intended for solid dosage forms.
Flakes	FLAK	Flakes	83	Small, thin pieces of ingredients or food stuffs, which may be aggregates of smaller particles (powder, grain etc.) or parts of a larger piece which has broken off.

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Dosage Form	Code	Abbreviation	C6	Comments
Description				
Fluid Extract	EXTR	FI Extract	14	A concentrated preparation of vegetable or animal drugs, extracted from the source material, concentrated by removal of the solvent, then adjusted to prescribed standards.
Foam	FOAM	Foam	39	A gas-bubble infused liquid or semi-solid vehicle with ingredients.
Gas	GAS	Gas	26	A liquid entirely in its vapor phase at one atmosphere of pressure because the ambient temperature is above its boiling point.
Gel	GEL	Gel	40	A semi-solid system consisting of either a suspension made up of small inorganic particles or large organic molecules interpenetrated by a liquid. May be either single-phase or two-phase gel systems. †
Gel Forming Solution	SOLG	Gel Form Soln	76	A solution when upon administration/instillation forms a gel.
Granules	GRAN	Granules	27	A small particle or grain. <sup>†</sup>
Granules Effervescent	GREF	Granules Effer	77	Granules (see granules) in a dry mixture which when placed in contact with water have the capability to release gas and cause effervescence.
Gum	GUM	Gum	28	An insoluble plastic material from various plant sources which when chewed, releases ingredients into the oral cavity.
Implant	IMPL	Implant	23	A solid drug form that is inserted into intact body tissue.

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Dosage Form	Code	Abbreviation	C6	Comments
Description				
Inhaler	INHA	Inhaler	24	A dose form that is an inhaler/inhalant but is not adequately described by other available dosage forms.
Injectable	INJ	Injectable	22	Unspecified injectable dose form. †
Insert	INST	Insert	99	A solid or semi-solid drug form intended for insertion into body cavity or site.
Intrauterine Device	IUD	IUD	53	A device inserted and left in the uterus to prevent effective conception. This device may contain and release an ingredient as part of its contraceptive design.
Jet-injector (Needleless)	JTAJ	Jet-injector	D7	A medication in a Jetinjector. A Jet-Injector is a non-electrically powered device that gives a hypodermic injection by means of a narrow, high velocity jet of fluid which can penetrate the surface of the skin and deliver the fluid to the body without a needle. Drug form unknown.
Jet-injector Kit (Needleless)	JTKT	Jet-inj Kit	F6	A medication in a Jet- injector (see Jet-injector) that is available as a kit.
Kit	KIT	Kit	64	Products with at least two different or discreet items (excluding diluents applicators and activation devices) in the same package, intended for dispensing as a unit.
Leaves	LEAV	Leaves	97	Organic material derived from the leafing parts of a plant or plant.
Liquid	LIQD	Liquid	09	Ingredient(s) present in a fluid state. †

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Dosage Form	Code	Abbreviation	C6	Comments
Description				
Liquid Extended- Release*	LQCR	Liquid ER	11	A liquid (see liquid) that has been formulated to allow for an extended release of the ingredient(s).
Liquid Therapy Pack	LQPK	Liqd Ther Pack	C4	Therapy pack with only liquid dose form.
Lotion	LOTN	Lotion	41	An unspecified liquid for external application which is commonly a suspension, emulsion or dispersion. †
Lozenge	LOZG	Lozenge	47	A solid preparation which is intended to dissolve or disintegrate slowly in the mouth (usually in a flavored, sweetened base).†
Lozenge on a Handle	LPOP	Loz on a Handle	84	A medicated lozenge on the end of a stick. Intended for oral administration.
Miscellaneous	MISC	Misc	63 or 00	A dose form not described by other database dose forms. Note: C6 values of "00" may also be used in GPIs having this dosage form. <sup>†</sup>
Nebulization Solution	NEBU	Nebu Soln	25	A solution (see solution) intended to be atomized into a fine mist for inhalation.
Oil	OIL	Oil	17	A liquid that is readily soluble in ether, but not in water. †
Ointment	OINT	Ointment	42	An oil-based semi-solid preparation intended for external application to the skin or mucous membranes.
Packet	PACK	Packet	30	A packet, sachet or unit- of-use of dry powder (see powder) or granules (see granules). <sup>†</sup>

Dosage Form Description	Code	Abbreviation	C6	Comments
Pad	PADS	Pad	43	A fabric based swath of cloth that may or may not be medicated with ingredients. †
Paste	PSTE	Paste	44	A semi-solid preparation intended for external application (thicker and stiffer than most ointments) or thick, stiff ointments that do not ordinarily flow at body temperature and therefore serve as protective coatings over the areas to which they are applied.
Patch	PTCH	Patch	59	A drug delivery system in the form of a patch that releases an ingredient (or ingredients) over time (frequency not specified).
Patch 24 HR	PT24	Patch 24HR	85	A patch (see patch) with a 24 hour dosing frequency.
Patch 72 HR	PT72	Patch 72HR	86	A patch (see patch) with a 72 hour dosing frequency.
Patch Twice Weekly	PTTW	Patch TW	87	A patch (see patch) with a twice-weekly dosing frequency.
Patch Weekly	PTWK	Patch Weekly	88	A patch (see patch) with a weekly dosing frequency.
Pellet	PLLT	Pellet	89	A small solid mass of ingredients made by compression or molding.

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Dosage Form	Code	Abbreviation	C6	Comments
Description				
Pen-injector	PEN	Pen-injector	D1	A medication in a Pen- injector. A Pen-injector is a device that provides a non-electrically-powered, mechanically-operated method of accurately injecting a dose of medicinal product from a medicinal cartridge, reservoir, or syringe through a manually- inserted single lumen hypodermic needle. Drug form unknown
Pen-injector Kit	PNKT	Pen-inj Kit	F4	A medication in a Pen- injector (see Pen-injector) that is available as a kit.
Powder	POWD	Powder	29	A mixture of dry, finely divided ingredients and/or chemicals. <sup>†</sup>
Powder Effervescent	PDEF	Powder Effer	78	Powder (see powder) which when placed in contact with water has the capability to release gas and cause effervescence.
Prefilled Syringe	PRSY	Prefilled Syr	E4	Medication in a prefilled syringe. Drug form unknown.
Prefilled Syringe Kit	PSKT	Prefill Syr Kit	F8	Medication in a prefilled syringe available as a kit.
Pudding	PUDG	Pudding	79	A sweet and flavored, thick, semi-solid food.
Ring	RING	Ring	90	A round, circular structure that may be flexible or rigid.
Shampoo	SHAM	Shampoo	45	A liquid soap or detergent used to clean the hair and scalp that is often used as a vehicle for dermatologic agents. †
Sheet	SHEE	Sheet	91	A solid dose form in a relatively thin layer of fiber or fabric. †

Dosage Form	Code	Abbreviation	C6	Comments
Description				
Solution	SOLN	Solution	20	A liquid preparation that contains one or more chemical substances dissolved, i.e., molecularly dispersed, in a suitable solvent or mixture of mutually miscible solvents.
Solution Auto- injector	SOAJ	Soln Auto-inj	D5	A solution in an Auto- injector. An Auto-injector is a device that uses a spring-loaded mechanism to drive a hypodermic needle into a patient to a predetermined depth below the skin surface.
Solution Cartridge	SOCT	Soln Cartridge	E2	Solution in a cartridge with or without a needle.
Solution Jet- injector	CTOS	Soln Jet-inj	D8	A solution in a jet- injector. A Jet-Injector is a non-electrically powered device that gives a hypodermic injection by means of a narrow, high velocity jet of fluid which can penetrate the surface of the skin and deliver the fluid to the body without a needle.
Solution Pen- injector	SOPN	Soln Pen-inj	D2	A solution in a Peninjector. A Pen-injector is a device that provides a non-electrically-powered, mechanically-operated method of accurately injecting a dose of medicinal product from a medicinal cartridge, reservoir, or syringe through a manually-inserted single lumen hypodermic needle.
Solution Prefilled Syringe	SOSY	Soln Pref Syr	E5	Solution in a prefilled syringe.

Dosage Form	Code	Abbreviation	C6	Comments
Description	0000	7 ibbi oviation		Commonts
Solution Reconstituted	SOLR	For Solution	21	Dry powder (see powder) or granules (see granules) which upon the addition of a suitable vehicle, yields a solution (see solution).
Solution Therapy Pack	SOPK	Soln Ther Pack	C5	Therapy pack with only solution dose form.
Spirit	SPRT	Spirit	92	Alcoholic or hydroalcoholic solutions of volatile substances
Stick	STCK	Stick	93	A dosage form prepared in a relatively long and slender often cylindrical form. †
Strip	STRP	Strip	61	A long, flat, narrow piece of material that may be impregnated or coated with testing reagents. †
Suppository	SUPP	Suppository	52	A solid body of various weights and shapes, adapted for introduction into the rectal, vaginal or urethral orifice of the human body; they usually melt, soften or dissolve at body temperature.
Suspension	SUSP	Suspension	18	A liquid preparation which consists of solid particles dispersed throughout a liquid phase in which the particles are not soluble.
Suspension Auto- injector	SUAJ	Susp Auto-inj	D6	A suspension in an auto- injector. An Auto-injector is a device that uses a spring-loaded mechanism to drive a hypodermic needle into a patient to a predetermined depth below the skin surface.
Suspension Cartridge	SUCT	Susp Cartridge	E3	Suspension in a cartridge with or without a needle.

Dosage Form	Code	Abbreviation	C6	Comments
Description				
Suspension Extended Release	SUER	Suspension ER	G1	A suspension which releases any part of a dose over an extended period of time due to the release characteristics of the suspension design. The release rate allows at least a reduction in dosing frequency (various unspecified intervals).
Suspension Jet- injector	LTUS	Susp Jet-inj	D9	A suspension in a jet- injector. A Jet-Injector is a non-electrically powered device that gives a hypodermic injection by means of a narrow, high velocity jet of fluid which can penetrate the surface of the skin and deliver the fluid to the body without a needle.
Suspension Pen- injector	SUPN	Susp-Pen-inj	D3	A suspension in a Peninjector. A Pen-injector is a device that provides a non-electrically-powered, mechanically-operated method of accurately injecting a dose of medicinal product from a medicinal cartridge, reservoir, or syringe through a manually-inserted single lumen hypodermic needle.
Suspension Prefilled Syringe	SUSY	Susp Pref Syr	E6	Suspension in a prefilled syringe.
Suspension Reconstituted	SUSR	For Suspension	19	A dry powder (see powder) or granules (see granules) which upon the addition of a suitable vehicle, yields a suspension (see suspension).†

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Dosage Form	Code	Abbreviation	C6	Comments
Description				
Suspension Reconstituted ER	SRER	For Susp ER	G2	A dry powder (see powder) or granules (see granules) which upon the addition of a suitable vehicle yields a suspension which releases any part of a dose over an extended period of time due to the release characteristics of the dosage form design. The release rate allows at least a reduction in dosing frequency (various unspecified intervals).
Suspension Therapy Pack	SUPK	Susp Ther Pack	C6	Therapy pack with only suspension dose form.
Swab	SWAB	Swab	94	A cotton or other fabric applicator that is used alone or attached to (usually wrapped around) the end of a stick.
Syrup	SYRP	Syrup	12	An oral solution containing high concentrations of sucrose, other sugars or sorbitol; the term has also been used to include any other liquid dosage form prepared in a sweet and viscid vehicle.
Tablet	TABS	Tablet	03	A solid dosage form containing ingredients with or without suitable diluents. †
Tablet Abuse- Deterrent	ТАВА	Tab Abuse Deter	A5	Tablet (see tablet dose form) with abusedeterrent properties or labeling that use physical or chemical barriers or delivery systems.

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Dosage Form	Code	Abbreviation	C6	Comments
Description				
Tablet Chewable	CHEW	Tablet Chewable	05	A tablet (see tablet) that is intended to be chewed and then swallowed. Includes chewable tablets that may be either swallowed whole or chewed, based on patient preference and tolerance, as long as the tablet is designed with an option to be chewed prior to swallowing.†
Tablet Chewable Extended Release	CHER	Tablet ER Chew	H2	A tablet (see tablet) that is intended to be chewed and then swallowed and releases any part of a dose over an extended period of time due to the release characteristics of the chewable tablet design. Includes chewable tablets that may be either swallowed whole or chewed, based on patient preference and tolerance, as long as the tablet is designed with an option to be chewed prior to swallowing.
Tablet Delayed Release	TBEC	Tablet DR	06	A tablet (see tablet) which is coated to prevent release of the ingredient(s) until it passes the low pH environment of the stomach in the gastrointestinal tract.

Dosage Form	Code	Abbreviation	C6	Comments
Description				
Tablet Delayed Release Disintegrating	TBDD	Tab DR Disint	Н3	A tablet (see tablet dose form) which disintegrates when placed upon the tongue or in the mouth and that utilizes coated particles that prevent release of the ingredient(s) until they pass the low pH environment of the stomach in the gastrointestinal tract.
Tablet Delayed Release Therapy Pack	TDPK	TBDR Ther Pack	B8	Therapy pack with only tablet delayed release dose form.
Tablet Disintegrating Soluble	TB3D	Tab Disint Sol	G8	A tablet designated to disintegrate in the mouth with a sip of liquid or dissolve in a liquid prior to administration (i.e. such as a 3-dimensional printed [3DP] tablet.
Tablet Disintegrating Soluble ER	TB3E	Tab Dis Sol ER	G9	An extended release tablet designed to disintegrate in the mouth with a sip of liquid prior to administration (i.e. such as a 3-dimensional printed [3DP] tablet.
Tablet Disintegrating	TBDP	Tablet Disintegrating	72	A tablet (see tablet) containing a drug (or drugs) which disintegrates when placed upon the tongue or in the mouth.†
Tablet Disintegrating Therapy Pack	TPPK	TBDP Ther Pack	B9	Therapy pack with only tablet disintegrating dose form.
Tablet Effervescent	TBEF	Tablet Effer	08	A tablet (see tablet) which releases gas when dissolved in water causing effervescence; it is intended to be dissolved or dispersed in water before administration.

Dosage Form	Code	Abbreviation	C6	Comments
Description				
Tablet ER 12 Hour Abuse-Deterrent	T12A	Tab 12HR Deter	Α7	Tablet Extended Release which is designed to release ingredients at a controlled rate (see tablet extended release 12 hour) with abuse-deterrent properties or labeling that use physical or chemical barriers or delivery systems. The dose form is designed to facilitate a 12 hour dosing frequency (interval).
Tablet ER 24 Hour Abuse-Deterrent	T24A	Tab 24HR Deter	A8	Tablet Extended Release which is designed to release ingredients at a controlled rate (see tablet extended release 24 hour) with abuse-deterrent properties or labeling that use physical or chemical barriers or delivery systems. The dose form is designed to facilitate a 24 hour dosing frequency (interval).
Tablet ER 12 Hour Therapy Pack	T2PK	TB12 Ther Pack	C2	Therapy pack with only tablet extended release 12 hour dose form.
Tablet ER 24 Hour Therapy Pack	T4PK	TB24 Ther Pack	C3	Therapy pack with only tablet extended release 24 hour dose form.
Tablet Extended- Release	TBCR	Tablet ER	04	A tablet (see tablet) which releases any part of a dose over an extended period of time due to the release characteristics of the tablet design. The release rate allows at least a reduction in dosing frequency (various unspecified intervals).

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Dosage Form	Code	Abbreviation	C6	Comments
Description	Jour	71551 GVIGUIGII		Commones
Tablet Extended Release 12 HR*	TB12	Tablet ER 12HR	74	A tablet (see tablet) which is designed to release ingredients at a controlled rate. The dose form is designed to facilitate a 12 hour dosing frequency (interval).
Tablet Extended Release 24 HR <sup>*</sup>	TB24	Tablet ER 24HR	75	A tablet (see tablet) which is designed to release ingredients at a controlled rate. The dose form is designed to facilitate a 24 hour dosing frequency.
Tablet Extended Release Abuse- Deterrent	TBEA	Tab ER Deter	A6	Tablet Extended Release (see tablet extended release) which releases any part of a dose over an extended period of time due to the release characteristics of the tablet design with abusedeterrent properties or labeling that use physical or chemical barriers or delivery systems.
Tablet Extended Release Disintegrating	TBED	Tab ER Disint	H4	A tablet (see tablet dose form) which disintegrates when placed upon the tongue or in the mouth and that utilizes particles that release over an extended period of time due to the release characteristics of the particles.
Tablet Extended Release Therapy Pack	TEPK	TBER Ther Pack	C1	Therapy pack with only tablet extended release dose form.
Tablet Soluble	TBSO	Tablet Soluble	73	A tablet (see tablet) that is usually dissolved in a liquid prior to administration.
Tablet Sublingual	SUBL	Tab Sublingual	07	A tablet (see tablet) that is administered sublingually.

Dosage Form Description	Code	Abbreviation	C6	Comments
Tablet Therapy Pack	TBPK	Tab Ther Pack	B7	Therapy pack with only tablet dose form.
Tampon	TAMP	Tampon	58	Pack or plug made of cotton, sponge or oakum; may contain a drug.
Tape	TAPE	Tape	46	A narrow woven fabric, or plastic, usually with an adhesive on one or both sides. <sup>†</sup>
Tar	TAR	Tar	95	A tarry substance.
Therapy Pack	THPK	Therapy Pack	B1	Therapy pack with multiple dose forms.
Tincture	TINC	Tincture	15	An alcoholic or hydroalcoholic solution prepared from vegetable materials or from chemical substances.
Troche	TROC	Troche	48	A discoid-shaped solid containing the medicinal agent in a suitable flavored base; troches are placed in the mouth where they slowly dissolve, liberating the active ingredients.
Wafer	WAFR	Wafer	31	A thin slice of material containing a medicinal agent.
Wax	WAX	Wax	96	Paraffin from an animal or insect source.

Note \* CR and SR designate controlled release dosage forms but do not quantify the type of release mechanism.

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 $<sup>^\</sup>dagger$  For Dosage Form Descriptions that include a '†', the Dosage Form for the product can differ from the dosage form that can be inferred from the C6 of the GPI. The marked records can change without notice.

# Appendix E: Wolters Kluwer Clinical Drug Information's Therapeutic Classification System

The Therapeutic Classification System (TCS) listings may be reproduced by printing the Record Types 1 through 3 from the optional Therapeutic Classification Reference File.

The current TCS listings are available at <a href="https://wds.medispan.com">https://wds.medispan.com</a>. To access these listings, you will need your User Name and Password.

If you need assistance accessing your User Name and Password, contact Customer Support.

# Appendix F: Inactives File Exceptions

The following exceptions are noted for the data contained within the Inactives file.

### **GPPC File Exception**

Generic Product Packaging Codes (GPPCs) that are associated to an NDC in the NDC File (MF2NDC) do not contain a corresponding record in the GPPC File (MF2GPPC).

Note

Approximately 447 GPPCs do not have a corresponding record in the GPPC File.

#### **Examples of GPPCs Not Included:**

- 46252AE2
- 21736D86

# **Labeler ID Exception**

Labeler IDs that are associated to an NDC in the NDC File (MF2NDC) do not contain a corresponding record in the Labeler File (MF2LAB).

Note

Approximately 193 Labeler IDs do not have a corresponding record in the Labeler ID File.

#### **Examples of Labeler IDs Not Included:**

- 9
- 27

## **Drug Descriptor Identifier Exception**

Drug Descriptor Identifiers (DDIDs) that are associated to an NDC in the NDC File (MF2NDC) do not have a corresponding record in the Drug Name File (MF2NAME).

Note

Approximately 272 Drug Descriptor Identifiers do not have a corresponding record in the Drug Name File.

#### Examples of Drug Descriptor Identifiers Not Included:

- 14988
- 37418

# **Drug Concept ID to Ingredient Set ID File Exception**

Some NDCs present in NDC File (MF2NDC) do not have ingredient set information in the Drug Concept ID to Ingredient Set ID File Exception (MF2SET).

Note

Approximately 10,000 NDCs do not have a corresponding record in the Drug Concept ID to Ingredient Set ID File.

#### Examples of Drug Concept ID to Ingredient Set IDs Not Included:

- 54868414301
- 00378018510

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