This product, USP32–NF27, is current from May 1, 2009 through April 30, 2010, as described below.

SIX-MONTH IMPLEMENTATION GUIDELINE

The United States Pharmacopeia–National Formulary and its Supplements become official six months after being released to the public. The USP–NF, which is released on November 1 of each year, becomes official on May 1 of the following year.

This change was adopted to give users more time to bring their methods and procedures into compliance with new and revised USP–NF requirements.

The table below describes the new official dates. The 2008 USP31–NF26, and the Supplements and Interim Revision Announcements (IRAs) to that edition, will be official until May 1, 2009, at which time the USP32–NF27 becomes official.

Publication	Release Date	Official Date	Official Until
USP32–NF27	Nov. 1, 2008	May 1, 2009	May 1, 2010 (except as superceded by Supplements, IRAs, and Revision Bulletins)
First Supplement	Feb. 1, 2009	Aug. 1, 2009	May 1, 2010 (except as superceded by Second Supplement, IRAs, and Revision Bulletins)
Second Supplement	June 1, 2009	Dec. 1, 2009	May 1, 2010 (except as superceded by IRAs and Revision Bulletins)
USP33–NF28	Nov. 1, 2009	May 1, 2010	May 1, 2011 (except as superceded by Supplements, IRAs, and Revision Bulletins)

IRAs will continue to become official on the first day of the second month of the Pharmacopeial Forum (PF) issue in which they are published as final. For instance, IRAs published as final in the May-June PF (issue 3) will become official on June 1. This table gives the details of the IRAs that will apply to USP31–NF26 and USP32–NF27.

IRA*	Release Date	Official Date	Revises
Jan. 1, 2009 IRA, PF 35 (1)	Jan. 1, 2009	Feb. 1, 2009	USP31–NF26 and its Supplements
Mar. 1, 2009 IRA, PF 35 (2)	Mar. 1, 2009	April 1, 2009	USP31–NF26 and its Supplements
May 1, 2009 IRA, PF 35 (3)	May 1, 2009	June 1, 2009	USP32–NF27
July 1, 2009 IRA, PF 35 (4)	July 1, 2009	Aug. 1, 2009	USP32–NF27 and First Supplement
Sept. 1, 2009 IRA, PF 35 (5)	Sept. 1, 2009	Oct. 1, 2009	USP32–NF27 and First Supplement
Nov. 1, 2009 IRA, PF 35 (6)	Nov. 1, 2009	Dec. 1, 2009	USP32–NF27 and its Supplements

Jan. 1, 2010 IRA, PF 36 (1)	Jan. 1, 2010	Feb. 1, 2010	USP32–NF27 and its Supplements
Mar. 1, 2010 IRA, PF 36 (2)	Mar. 1, 2010	April 1, 2010	USP32–NF27 and its Supplements

*NOTE—Beginning January 1, 2007, USP ceased identifying IRAs numerically (First, Second, etc.) and instead now designates them by the date on which they are published.

Revision Bulletins published on the USP website will continue to become official immediately upon publication, unless the Revision Bulletin specifies otherwise.

Revisions that contain a specific official date shall continue to become official upon such specified date, which supercedes the general official date for the publication.

For more information about the change in official dates, please visit the USP website at http://www.usp.org.

NOTICE AND WARNING

Concerning U.S. Patent or Trademark Rights—The inclusion in The United States Pharmacopeia or in the National Formulary of a monograph on any drug in respect to which patent or trademark rights may exist shall not be deemed, and is not intended as, a grant of, or authority to exercise, any right or privilege protected by such patent or trademark. All such rights and privileges are vested in the patent or trademark owner, and no other person may exercise the same without express permission, authority, or license secured from such patent or trademark owner.

Concerning Use of USP or NF Text—Attention is called to the fact that USP and NF text is fully copyrighted. Authors and others wishing to use portions of the text should request permission to do so from the Secretary of the USPC Board of Trustees.

12601 Twinbrook Parkway, Rockville, MD 20852

ISSN: 1930-2932 ISBN: 1-889788-73-9

Mission and Preface
USP 32–NF 27

This section provides background information on the United States Pharmacopeial Convention (USP), as well as general information about the 32nd revision of the United

States Pharmacopeia (USP 32) and the 27th edition of the National Formulary (NF 27). Additional official information about the specific uses of these texts is provided in the General Notices and Requirements section, which has been significantly revised (see www.usp.org/GeneralNotices for a summary of revisions).

MISSION STATEMENT

USP–NF is published in continuing pursuit of the mission of USP: To improve the health of people around the world through public standards and related programs that help ensure the quality and safety of medicines and foods.

HISTORY

On January 1, 1820, 11 physicians met in the Senate Chamber of the U.S. Capitol building to establish a pharmacopeia for the United States. These practitioners sought to create a compendium of the best therapeutic products, give them useful names, and provide recipes for their preparation. Nearly a year later, on December 15, 1820, the first edition of The Pharmacopoeia of the United States was published. Over time, the nature of the United States Pharmacopeia (USP) changed from being a compendium of recipes to a compendium of documentary standards that increasingly are allied with reference materials, which together establish the identity of an article through tests for strength, quality, and purity. The publishing schedule of the USP also changed over time. From 1820 to 1942, the USP was published at 10-year intervals; from 1942 to 2000, at 5-year intervals; and beginning in 2002, annually.

In 1888, the American Pharmaceutical Association published the first national formulary under the title The National Formulary of Unoficinal [sic] Preparations (NF). Both the USP and the NF were recognized in the Federal Food and Drugs Act of 1906 and again in the Federal Food, Drug, and Cosmetic Act 1938. In 1975, USP acquired the National Formulary (NF), which now contains excipients standards with references to allied reference materials. Today, USP continues to develop USP and NF through the work of the Council of Experts into compendia that provide standards for articles based on advances in analytical and metrological science. As these and allied sciences evolve, so do USP and NF.

USP 32–NF 27

USP 32–NF 27 text is official May 1, 2009, unless otherwise noted. USP–NF contains official substance and preparation (product) monographs. The terms official substance and official preparation are defined in the General Notices of this Pharmacopeia. With few exceptions, all articles for which monographs are provided in USP 32–NF 27 are legally

marketed in the United States or are contained in legally marketed articles.

A USP–NF monograph for an official substance or preparation includes the article's definition; packaging, storage, and other requirements; and a specification. The specification consists of a series of universal (description, identification, impurities, assay) and specific tests, one or more analytical procedures for each test, and acceptance criteria. Ingredients are defined as either drug substances or excipients. An excipient is any component, other than the active substance(s), intentionally added to the formulation of a dosage form. Excipients are not necessarily inert. Drug substances and excipients may be synthetic, semisynthetic, drawn from nature (natural source), or manufactured using recombinant technology. Larger molecules and mixtures requiring a potency test are usually referred to as biologicals or biotechnological articles.

USP 32–NF 27 contains approximately 4,303 monographs and more than 220 General Tests and Assays (General Chapters numbered 1,000 and below) and USP General Information Chapters (numbered above 1,000). General Chapters provide frequently cited procedures, sometimes with acceptance criteria, in order to compile into one location repetitive information that appears in many monographs. New and revised monographs and General Chapters and obsolete matter deleted from this edition are indicated in the Admissions section.

USP 32–NF 27 Organization— USP 32–NF 27 is printed as a three-volume set. Volume 1 includes front matter (Mission and Preface, People, Governance pages and websites, Admissions/Annotations, and Commentary). It also includes USP General Notices, General Chapters, Dietary Supplement chapters, Reagents, Reference Tables, Dietary Supplement monographs, NF Admissions, Excipients, and NF monographs. Volume 2 includes USP monographs A–L, and Volume 3 includes USP monographs M–Z. Volumes 2 and 3 also include the USP General Notices and the Guide to General Chapters, and all three volumes include the full index. General Chapters specific to dietary supplements are included in numerical order with the rest of the General Chapters in USP. Excipient monographs usually are presented in NF but also may appear in USP with suitable cross-referencing when they are also drug substances. The Excipients section (Volume 1) presents a tabulation of excipients by functional category.

USP 32–NF 27 Spanish Edition— In 2006, USP began providing an official Spanish edition of USP–NF. Maintenance of this edition follows the same revision approaches as the English edition.

Revisions— USP–NF is continuously revised. Revisions are presented annually, in twice-yearly Supplements, in Interim Revision Announcements (IRAs), and in Revision Bulletins (on the USP website).

Supplements— The First Supplement to USP 32–NF 27 will be published in February

2009 and will become official in August 2009. The Second Supplement will be published in June 2009 and will become official in December 2009. Users of USP print products must retain Supplements and subscriptions to Pharmacopeial Forum (PF) in order to have up-to-date information. The USP–NF online version is updated with each Supplement or annual revision. Each time a new edition or Supplement is released during the subscription period, a new CD-ROM will be issued. The Index in each Supplement is cumulative and includes citations to the annual revision and, for the Second Supplement, citations to the First Supplement. The contents of the two Supplements are integrated into the annual edition of the following year, along with new official revisions that have been adopted since the Second Supplement to the previous compendia.

Interim Revision Announcements (IRAs)— IRAs contain revisions that become official in the interval between publication of the annual revision and Supplements, and thus provide an expedited mechanism for making revisions official. They appear in USP's bimonthly journal, Pharmacopeial Forum (PF), with the official date noted in the publication. They are subsequently incorporated into the next published Supplement or annual revision, although their official dates may precede the official date of that publication.

Revision Bulletins— If the circumstances require immediate publication of official text, a proposal or postponement may be published through a Revision Bulletin. Revision Bulletins are posted on the USP website and published in the next USP-NF or Supplement, as applicable. Revision Bulletin official dates are specified in the individual Revision Bulletin.

Pharmacopeial Forum (PF)— Each PF contains several sections. The Policies and Announcements section provides information about publication and comment deadlines, USP news, and summaries of issues discussed by the Council of Experts and its Expert Committees. Proposals for revision are presented as In-Process Revisions and represent draft revisions that are expected to advance to official status pending final review and approval by the relevant Expert Committee.

PF also includes Pending and Canceled Proposals and a Harmonization section. The Stimuli to the Revision Process section presents reports or statements of authoritative bodies, scientific articles relevant to compendial issues, general commentaries by interested parties, and summaries of comments received in response to policy initiatives. PF concludes with sections containing Nomenclature, Index, and Chromatographic Reagents used in USP–NF and PF. Each issue of PF also provides a cumulative index for the given calendar year.

Symbols Indicating Change to Official Text— Symbols identify the beginning and end of each revision. The following table summarizes the types of symbols and the associated subscripts used in USP publications:

Revision Type	Symbol	Subscript

Interim Revision Announcement	•new text•1	1–6
Revision Bulletin	•new text(RB 01-Jan-2009)	(RB 1-Jan-2009)
Text deletion	• •1 or ▪ ▪1S (USP31) or ▲ ▲USP31	
Adopted in Supplement	▪new text▪1S (USP31)	1 or 2S (USP annual edition)
Adopted in USP–NF	▲new text▲USP31	USP annual edition

Interim revisions are shown with new text (if any) enclosed in circles, •new text•1. New text revised in Revision Bulletins is enclosed in circles, •new text(RB dd-mm-yyy). Text enclosed in squares, ▪new text▪1S (USP31), has already been adopted in a Supplement. Text that has been adopted in the USP–NF is enclosed in triangles, ▲new text▲USP32. Where the symbols appear together with no enclosed text, such as • •1 or ▪ ▪1S (USP31), it means that text has been deleted and no new text has been proposed to replace it.

In all revisions, the closing symbol is accompanied by a subscript number or date that indicates the Interim Revision Announcement (IRA), Revision Bulletin, or Supplement in which the revision first appeared. An example of a revision that was officially adopted in the Second Interim Revision Announcement would be •2; an example of a revision that was officially adopted in the Revision Bulletin on June 18, 2008, would be (RB 18-Jun-2008). An example of revision that was officially adopted in the Second Supplement to USP 31 would be ▪2S (USP31). Last, an example of a revision that was officially adopted in USP 32–NF 27 would be ▲USP32. The following table shows symbols and official dates for Interim Revision Announcements and Supplements to USP 32–NF 27:

USP 32–NF 27 Revision Document			
Supplement	Interim Revision Announcement	Official Date	Symbols
	35(1)	Feb. 1, 2009	•and•1
	35(2)	Apr. 1, 2009	•and•2
	35(3)	June 1, 2009	•and•3
1		Aug. 1, 2009	▪and▪1S (USP32)
	35(4)	Aug. 1, 2009	•and•4
	35(5)	Oct. 1, 2009	•and•5
2		Dec. 1, 2009	▪and▪2S (USP32)
	35(6)	Dec. 1, 2009	•and•6

Chemical Names and CAS Registry Numbers— Chemical subtitles given in the monographs are index names used by the Chemical Abstracts Service (CAS) of the American Chemical Society. They are provided only in monographs in which the titles specify substances that are definable chemical entities. The first subtitle is the inverted form of the systematic chemical name developed by CAS. This is presented in

accordance with the rules established over the years by the International Union of Pure and Applied Chemistry (IUPAC) and the International Union of Biochemistry, and this form is employed in the current issues of Chemical Abstracts (CA). The second subtitle, given in uninverted form, is of a systematic type formerly used in CA. It is identical with, or closely resembles, the chemical name sanctioned and employed by IUPAC and by the World Health Organization (WHO). IUPAC names make generous use of nonsystematic and semisystematic (often referred to as “trivial”) names and qualifying terms, all of which impede electronic manipulation. In contrast, CAS names are fully systematic for most substances and are amenable to search and retrieval. The two subtitles referred to above are frequently identical, and a CAS synonym is occasionally supplied as a third subtitle. Monographs with chemical subtitles generally also carry CAS registry numbers. These italicized, bracketed numbers function independently of nomenclature as invariant numerical designators of unique, unambiguous chemical substances in the CAS registry and thus are convenient and widely used.

Print and Electronic Presentations— All USP–NF publications are available in print form. In addition, USP–NF and its two annual Supplements are available in compact disc (CD) and online versions. The CD version makes USP–NF accessible to users on their computer hard drives. The online format allows individual registered users to access the online format through the Internet. Both electronic formats provide access to official USP–NF content, along with extensive search options. The electronic formats are cumulatively updated to integrate the content of Supplements. Searchable electronic versions of PF and of the USP Dictionary also are available.

USP GOVERNANCE, STANDARDS-SETTING, AND ADVISORY BODIES

USP's governing, standards-setting, and advisory bodies include the USP Convention, the Board of Trustees, the Council of Experts and its Expert Committees, Advisory Panels, and staff. Additional volunteer bodies include Stakeholder Forums, Project Teams, and Advisory Groups, which act in an advisory capacity to provide input to USP's governing, standards-setting, and management bodies.

USP Convention— USP's direction and priorities are determined by more than 400 Convention members divided into nine categories (see the People section). Eligible organizations within each membership category are invited to appoint a representative. Convention composition is determined to ensure suitable representation of those sections of the health care system that are influenced by, and in turn influence, USP's activities. Convention members elect USP's President, Treasurer, and other members of the Board of Trustees as well as the Council of Experts. They also vote on resolutions to guide USP's scientific policy and public health initiatives and update, as needed, USP's Constitution and By-Laws. The next meeting of the USP Convention is scheduled for April

2010 in Washington, DC.

Board of Trustees— USP's Board of Trustees is entrusted with management of the business affairs, finances, and property of USP. During its five-year term, the Board defines USP's strategic direction through its key policy and operational decisions. A listing of the members of the 2005–2010 Board of Trustees appears in the People section.

Council of Experts— The Council of Experts is the standards-setting body of USP. It is composed of 57 Expert Committee Chairs elected to five-year terms by USP's Convention members. A Nominating Committee, consisting of the Chair of the Council of Experts, the Convention President, and the Vice Chair of the Nominating Committee for the Council of Experts, nominates individuals who are subsequently elected by the members of the Council of Experts to serve as Expert Committee members. Collectively, the Expert Committee Chairs and members comprise more than 500 volunteers drawn from 50 countries. The 41 Standards Expert Committees are responsible for the content of USP–NF, the Food Chemicals Codex, and associated publications (see Figure 1) and organized in Collaborative Groups for topics of common interest. The Information Expert Committees focus on development of Model Guidelines for the Medicare Modernization Act and other information activities. The Executive Committee of the Council of Experts (see the People section) provides overall direction, is an appeals body, and performs other functions that support the Council's operations.

Figure 1. Organization of the 2005–2010 USP Council of Experts

Advisory Panels to the Council of Experts— The Chair of the Council of Experts may appoint Advisory Panels to assist the Council of Experts in reaching scientific decisions and implementing new USP directives relating to USP–NF. A listing of Advisory Panels is provided in the People section. This list changes frequently as the work of Advisory Panels concludes and new ones start their deliberations. There are more than 350 Advisory Panel members who contribute to the standards-setting activities of the Council of Experts.

Stakeholder Forums and Project Teams— USP has formed several domestic and international Stakeholder Forums and Project Teams in the 2005–2010 cycle to exchange information and receive comment on USP's standards-setting activities. Depending on the topic, a stakeholder forum may form project teams to work on selected topics. USP has

also formed country and regional Stakeholder Forums. The following are lists of Stakeholder Forums for the 2005–2010 cycle.

Domestic Stakeholder Forums (United States and Canada)

- Prescription/Nonprescription
- Biologics and Biotechnology
- Compounding
- Dietary Supplements
- Food Ingredients
- Patient Safety

International Stakeholder Forums

- Europe
- India
- Latin America

USP also conducts Annual Scientific Meetings in the United States, India, China, Latin America, and the Middle East/North Africa.

Staff— USP maintains a staff of over 500 scientists, professionals, and administrative personnel at its Rockville, Maryland, headquarters. Additional staff members are located at the account management office in Basel, Switzerland, and laboratory complexes in Hyderabad, India; Shanghai, China; and São Paolo, Brazil.

RULES AND PROCEDURES

Governing Documents— USP–NF standards are recognized widely because they are authoritative and science-based and are established by a transparent and credible process. See the Articles of Incorporation section in this book; the Constitution and Bylaws and the Rules and Procedures of the 2005–2010 Council of Experts are available on USP's website (www.usp.org). Collectively, these documents serve USP volunteers and staff as the governing principles for USP's standards-setting activities.

Conflicts of Interest— USP's Conflict of Interest provisions require all members of the Council of Experts, its Expert Committees, Advisory Panels, Board of Trustees, and key staff to disclose significant financial interests in companies or other entities that are subject to USP–NF standards or that may be affected by USP–NF information. Members of the Board of Trustees, Council of Experts, and related bodies are not allowed to vote on any matter in which they have a conflict of interest or the appearance of a conflict of interest.

Confidentiality and Document Disclosure— Members of the Council of Experts, Expert Committees, and Advisory Panels sign confidentiality agreements, in keeping with the

confidentiality provisions of the Rules and Procedures of the Council of Experts. The USP Document Disclosure Policy, available on USP's website, contributes to the transparency of the standards-setting process by making information available to the public, yet provides protection to manufacturers and others who submit confidential information to USP.

Authority for Publication— USP–NF is published in accordance with Chapter VI, Section 8, of the USP Bylaws, which states, “The Board of Trustees shall authorize the revision and release of text to the United States Pharmacopeia and the National Formulary. Upon approval of the content by the Council of Experts, in accordance with the rules and procedures adopted under Section 9, the Board of Trustees shall then act upon releasing the text and upon designating the date when it is to become official, said date to be reasonably distant from the date of its release. The Executive Vice President–CEO shall, annually or more frequently, upon specific request of the Board of Trustees, certify that the information contained in the United States Pharmacopeia, National Formulary, or other authorized publications has been prepared in accordance with the rules and procedures under Section 9.”

USP–NF REVISION PROCESS

Public Participation— Although USP's Council of Experts is the ultimate decision-making body for USP–NF standards, these standards are developed by an exceptional process of public involvement and substantial interaction between USP and its stakeholders, both domestically and internationally. Participation in the revision process results from the support of many individuals and groups and also from scientific, technical, and trade organizations.

Requests for revision of monographs, either new monographs or those needing updating, contain information submitted voluntarily by manufacturers and other interested parties. At times USP staff may develop information to support a monograph Request for Revision. USP has prepared a document titled Guideline for Submitting Requests for Revision to USP–NF (available at www.usp.org, click on USP–NF). Via PF, USP solicits and encourages public comment on these monographs, General Chapters, and other draft documents. USP scientific liaisons to Expert Committees review these responses and create draft proposals that are provided to the Council of Experts. These drafts become official when Expert Committees ballot to make them official in USP–NF. Thus, the USP standards-setting process gives those who manufacture, regulate, and use therapeutic products the opportunity to comment on the development and revision of USP–NF standards. Because of the voting process and its special link to the U.S. government in law, USP is not considered a voluntary, consensus standards-setting body. Figure 2 shows the public review and comment process and its relationship to standards

development.

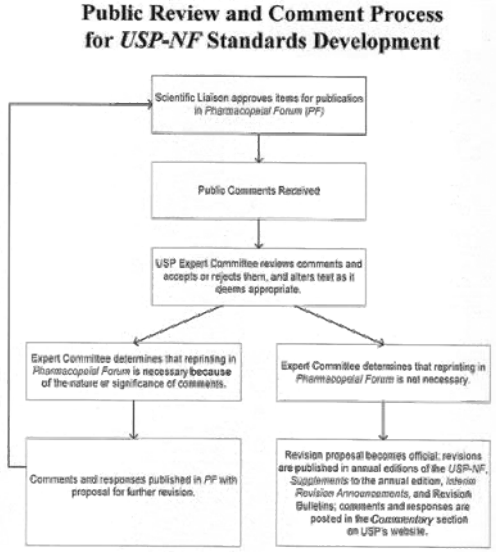

Figure 2. Public Review Process

Working with the Food and Drug Administration (FDA)— As specified in U.S. law, USP works with the Secretary of the Department of Health and Human Services in many ways. Principal agencies in the Department for this work are the Food and Drug Administration and the Centers for Medicare and Medicaid Services. The FDA Liaison Program allows FDA representatives to participate in Expert Committee meetings, enabling continuing interactions between FDA scientific staff and Expert Committee activities. Staff in the FDA Centers who are responsible for review of compendial activities provide specific links and opportunities for exchange of comments. Mr. Larry A. Ouderkirk in the Center for Drug Evaluation and Research provides a primary compendial link between FDA and USP.

LEGAL RECOGNITION

Recognition of USP–NF— USP–NF is recognized by law and custom in many countries throughout the world. In the United States, the federal Food, Drug, and Cosmetic Act (FD&C Act) defines the term “official compendium” as the official USP, the official NF, the official Homeopathic Pharmacopeia of the United States, or any supplement to them. FDA may enforce compliance with official standards in USP–NF under the adulteration and misbranding provisions of the FD&C Act. These provisions extend broad authority to FDA to prevent entry to or remove designated products from the United States market on the basis of standards in the USP–NF.

The identity of an official article, as expressed by its name, is established if it conforms in all respects to the requirements of its monograph and other relevant portions of the compendia. The FD&C Act stipulates that an article may differ in strength, quality, or purity and still have the same name if the difference is stated on the article's label. FDA requires that names for articles that are not official must be clearly distinguishing and

differentiating from any name recognized in an official compendium. Official preparations (a drug product, a dietary supplement including nutritional supplements, or a finished device) may contain additional suitable ingredients. (See General Notices.)

Drugs— USP's goal is to have substance and preparation (product) monographs in USP–NF for all FDA-approved drugs, including biologics, and their ingredients. USP also develops monographs for therapeutic products not approved by FDA, e.g., pre-1938 drugs, dietary supplements, and compounded preparations. Although submission of information needed to develop a monograph by the Council of Experts is voluntary, compliance with a USP–NF monograph, if available, is mandatory.

Biologics— In the United States, although some biologics are regulated under the provisions of the Public Health Service Act (PHSA), provisions of the FD&C Act also apply to these products. For this reason, products approved under the PHSA should comply with the adulteration and misbranding provisions of the FD&C Act at Section 501(b) and 502(g) and, thus, should conform to applicable official monographs in USP–NF.

Medical Devices— Section 201(h) of the FD&C Act defines a device as an instrument, apparatus, similar article, or component thereof recognized in USP–NF. Section 502(e) of the FD&C Act defines the established name of a device in the absence of an FDA designation of the official name as the official title in an official compendium. Despite these statutory provisions, there is no comparable recognition of USP's standards-setting authority and ability to define a medical device as exists for other FDA-regulated therapeutic products. Under authority granted by the Food and Drug Administration Modernization Act of 1997, the Center for Devices and Radiological Health recognizes national and international standards, including some USP tests and assays, for medical devices.

Dietary Supplements— The Dietary Supplement Health and Education Act of 1994 amendments to the FD&C Act name USP and NF as the official compendia for dietary supplements. The amendments also provide that a dietary supplement may be deemed misbranded if it is covered by a monograph in an official compendium, is represented as conforming to this monograph, but fails to conform. The dietary supplement must be represented as conforming to a USP–NF dietary supplement monograph in order for the compendial standards to apply. This contrasts with pharmaceutical products, wherein conformance to the monograph is mandatory whether or not the product claims to conform.

Compounded Preparations— Preparation monographs provide information or standards applicable in compounding. Compounding means the preparation, mixing, assembling, packaging, or labeling of a drug or device or other article, as the result of a practitioner's order or in anticipation of such an order based on routine, regularly observed prescribing patterns. Standards in USP–NF for compounded preparations may be enforced at both

the state and federal levels, e.g., if a practitioner writes a prescription for a compounded preparation that is named in a USP–NF monograph, the preparation, when tested, must conform to the stipulations of the monograph so named.

Nomenclature— In the United States, FDA has authority to establish names for drug products and ingredients and to determine proper names for biologics. In most cases, however, FDA works with the United States Adopted Names (USAN) Council to determine names for drug and biological substances and with USP to determine drug product names. Oversight of proprietary names and proper names is the responsibility of FDA, working with applicants.

The USAN Council's program began in 1961 by providing ingredient names for drugs prior to their marketing. USP participates in this activity, together with the American Medical Association, the American Pharmacists Association, and FDA. The Council's output is incorporated, along with other names for drugs (including generic, proprietary, and chemical names and code designations), in the USP Dictionary of USAN and International Drug Names. Since 1988 this publication has been recognized by federal regulation as the source of established names for drug substances in the United States.

Drug product names can be established by FDA, but more often are developed cooperatively by FDA and the USP Council of Experts' Nomenclature Expert Committee. The names developed by this Expert Committee are used as the titles of the relevant monographs, and as such are recognized as the “established names” for drug products under section 502(e)(3) of the FD&C Act. The USP Drug Nomenclature Committee was formed in 1986 to supplement the Executive Committees of the Drug Standards Division and the Information Division and to prevent any inconsistency regarding nomenclature. Following the 2000 meeting of the USP Convention, the responsibilities for devising and, when necessary, revising labeling requirements were delegated to this Expert Committee, which is now named the Nomenclature Expert Committee. The Expert Committee's work does not overlap that of the USAN Council. Rather, it is complementary and is concerned with standardization of compendial names, particularly dosage form names, and names for combination drug products.

HARMONIZATION ACTIVITIES

Pharmacopeial Discussion Group— USP harmonizes pharmacopeial excipient monographs and General Chapters through the Pharmacopeial Discussion Group (PDG), which includes representatives from the European, Japanese, and United States pharmacopeias, and WHO (as an observer). According to the PDG definition, “a pharmacopeial general chapter or other pharmacopeial document is harmonized when a pharmaceutical substance or product tested by the document's harmonized procedure yields the same results, and the same accept/reject decision is reached.” General

Information Chapter 〈1196〉, Pharmacopeial Harmonization, provides (1) the PDG Policy Statement, (2) the PDG Working Procedures and a definition of each stage of harmonization, (3) a discussion, (4) a status report, and (5) a glossary.

OTHER USP–NF RELATED PUBLICATIONS

Chromatographic Reagents— This comprehensive reference provides detailed information needed to conduct chromatographic procedures found in USP–NF. Chromatographic Reagents lists the brand names of the column reagents cited in every proposal for new or revised gas- or liquid-chromatographic analytical procedures that have been published in PF since 1980. Chromatographic Reagents also helps to track which column reagents were used to validate analytical procedures that have become official. The branded column reagents list is updated bimonthly in PF.

USP Pharmacists' Pharmacopeia— USP–NF is directed primarily to pharmaceutical and dietary supplement manufacturers, although it contains many monographs and allied text useful for compounding practitioners. To better accommodate the needs of these practitioners and more generally the needs of the pharmacy community, USP has made available the USP Pharmacists' Pharmacopeia. This text provides pharmacy-relevant abridged official text from the USP–NF as well as authorized information. The former refers to standards for official articles; the latter is more general information designed to be useful to practitioners. Both types of text are developed under the Rules and Procedures of the Council of Experts. The USP Pharmacists' Pharmacopeia is available both in print and in a web-based version.

USP Dictionary— The USP Dictionary of USAN and International Drug Names provides in a single volume the most up-to-date United States Adopted Names of drugs; official USP–NF names; nonproprietary, brand, and chemical names; graphic formulas; molecular formulas and weights; CAS registry numbers and code designations; drug manufacturers; and pharmacologic and therapeutic categories. The Dictionary helps to ensure the accuracy of the following: product labeling; reports, articles, and correspondence; FDA regulatory filings; and pharmaceutical package inserts. It is published annually (latest edition April 2008) and is recognized by FDA as the official source for established drug names (See Nomenclature section.)

USP Catalog— When referenced in a compendial procedure, use of official USP–NF Reference Standards promotes uniform quality of drugs and supports first-, second-, and third-party testing of all manufactured and compounded articles. The publication listing the collection of official USP–NF Reference Standards can be accessed on the USP website at www.usp.org and is available in print form by contacting USP Sales and Marketing staff at 301-816-8237. The listing identifies new items, replacement lots, lots of a single item that are simultaneously official, lots deleted from official status, and a preview of items

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Articles of Incorporation

In May of 1900, the USP Board of Trustees was directed by the Convention to incorporate the USP organization under the laws of the District of Columbia. Because the District of Columbia required that the majority of officers subscribing to the Certificate of Incorporation be residents, the filing was slightly delayed in order to appoint appropriate representatives. Nevertheless, the articles of incorporation were prepared, appropriately signed, and finally filed on July 11 of that year. The original certificate reads as follows:

Certification of Incorporation

This is to certify that we, whose names are hereunto subscribed, citizens of the United States, of full age, and a majority citizens of the District of Columbia, do associate ourselves together pursuant to the provisions of sections 545–552 inclusive of the Revised Statutes of the United States relating to the District of Columbia and of the Act of Congress to amend the same, approved the twenty-third day of April 1884, under the corporate name of The United States Pharmacopeial Convention.

This Association is organized for a period of nine hundred and ninety-nine years. The particular objects and business of this Association are the encouragement and promotion of the science and art of medicine and pharmacy by selecting by research and experiment and other proper methods and by naming such materials as may be properly used as medicines and drugs with formulas for their preparation; by establishing one uniform standard and guide for the use of those engaged in the practice of medicine and pharmacy in the United States whereby the identity, strength, and purity of all such medicines and drugs may be accurately determined, and for other like and similar purposes; and by printing and distributing at suitable intervals such formulas and the results of such and similar selections, names and determinations among the members of this Association, pharmacists, and physicians generally in the United States and others interested in pharmacy and medicine.

The management and control of the affairs, funds, and property of this Association for the first year of its existence shall be vested in a Board of Trustees consisting of the seven following persons:

Albert E. Ebert. George W. Sloan.

Samuel A.D. Sheppard.
William S. Thompson.
Charles E. Dohme.
Horatio C. Wood.
Charles Rice.

In testimony whereof we have hereunto set our hands and affixed our seals this seventh day of July, 1900.

William S.Thompson.	[SEAL]	Murray G. Motter.	[SEAL]
G. Lloyd Magruder.	[SEAL]	William M. Mew.	[SEAL]
John T. Winter.	[SEAL]	Frank M. Criswell.	[SEAL]
Thomas C. Smith.	[SEAL]		

Constitution and Bylaws

The Constitution and Bylaws that had been previously located in this section are now available at http://www.usp.org/aboutUSP/governance/constitutionAndBylaws/.

Rules, Procedures, and Policies

Rules and Procedures of the 2005–2010 Council of Experts

The Rules and Procedures that had been previously located in this section are now available at http://www.usp.org/aboutUSP/governance/policies/rulesAndProcedures/.

USP Policies

The policies that had been previously located in this section are now available at http://www.usp.org/aboutUSP/governance/policies/overview.html.

Admissions

Articles Admitted to USP 32 by Supplement

First Supplement (August 1, 2008)

GENERAL CHAPTERS

《130》 Protein A Quality Attributes
《1058》 Analytical Instrument Qualification
《503》 Acetic Acid in Peptides

DIETARY SUPPLEMENTS

Cat's Claw
Cat's Claw Capsules
Cat's Claw Tablets
Powdered Cat's Claw
Powdered Cat's Claw Extract
Fish Oil Containing Omega-3 Acids
Fish Oil Containing Omega-3 Capsules

USP MONOGRAPHS

Acarbose
Acitretin
Acitretin Capsules
Estradiol Benzoate
Fludarabine Phosphate Injection
Galantamine Hydrobromide

Biological Indicators for Moist Heat, Dry Heat, and Gaseous Modes of Sterilization, Nonpaper Carriers
Biological Indicators for Moist Heat, Dry Heat, and Gaseous Modes of Sterilization, Liquid Spore Suspensions
Calcium Carbonate and Magnesia Chewable Tablets
Cilostazol Tablets
Diclofenac Sodium Extended-Release Tablets
Eprinomectin
Esomeprazole Magnesium
Galantamine Tablets
Glimepiride Tablets
Ipratropium Bromide
Levalbuterol Hydrochloride
Levalbuterol Inhalation Solution
Lipid Injectable Emulsion
Omeprazole Magnesium
Sumatriptan Succinate
Terbinafine Hydrochloride

Second Supplement (December 1, 2008)

GENERAL CHAPTERS

《525》 Sulfur Dioxide
《1125》 Nucleic Acid-Based Techniques—General
《1126》 Nucleic Acid-Based Techniques—Extraction, Detection, and Sequencing
《1127》 Nucleic Acid-Based Techniques—Amplification
《1129》 Nucleic Acid-Based Techniques—Genotyping
《1130》 Nucleic Acid-Based Techniques—Approaches for Detecting Trace Nucleic Acids (Residual DNA Testing)

DIETARY SUPPLEMENTS

Powdered Bilberry Extract
Powdered Decaffeinated Green Tea Extract

USP MONOGRAPHS

Bicalutamide
Bovine Acellular Dermal Matrix
Cefaclor Chewable Tablets
Colestipol Hydrochloride Tablets
Cyromazine
Didanosine Tablets for Oral Suspension
Dinoprost Tromethamine Injection
Enoxaparin Sodium
Enoxaparin Sodium Injection
Fulvestrant
Ivermectin and Clorsulon Injection
Ivermectin Injection
Ivermectin Paste
Ivermectin Tablets
Ivermectin Topical Solution
Mycophenolate Mofetil
Raloxifene Hydrochloride
Raloxifene Hydrochloride Tablets
Sevoflurane
Valganciclovir Hydrochloride

Changes in Official Titles

The following title changes are official May 1, 2009

New Title	Former Title
《61》 Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests	《61》 Microbial Limit Tests

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〈62〉 Microbiological Examination of Nonsterile Products:
Tests for Specified Microorganisms

〈1111〉 Microbiological Examination of Nonsterile
Products: Acceptance Criteria for Pharmaceutical Preparations
and Substances for Pharmaceutical Use

〈1111〉 Microbiological Attributes of Nonsterile Pharmaceutical
Products

The following title changes are official February 1, 2010

New Title	Former Title
Alumina, Magnesia, and Calcium Carbonate Chewable Tablets	Alumina, Magnesia, and Calcium Carbonate Tablets
Alumina, Magnesia, Calcium Carbonate, and Simethicone Chewable Tablets	Alumina, Magnesia, Calcium Carbonate, and Simethicone Tablets
Alumina, Magnesia, and Simethicone Chewable Tablets	Alumina, Magnesia, and Simethicone Tablets
Calcium Carbonate, Magnesia, and Simethicone Chewable Tablets	Calcium Carbonate, Magnesia, and Simethicone Tablets
Dihydroxyaluminum Sodium Carbonate Chewable Tablets	Dihydroxyaluminum Sodium Carbonate Tablets
Magaldrate and Simethicone Chewable Tablets	Magaldrate and Simethicone Tablets
Phenytoin Chewable Tablets	Phenytoin Tablets
Thiabendazole Chewable Tablets	Thiabendazole Tablets

Revisions Appearing in USP 32 That Were Not Included in USP 31 Including Supplements

[note—The articles included in this list are noted in the book with the following symbols ▲▲USP32. This applies to new articles as well as sections of existing items that have been revised.]

New Articles Appearing in USP 32

DIETARY SUPPLEMENT MONOGRAPHS

Arginine Capsules

Arginine Tablets

Curcuminoids

Curcuminoids Capsules

Curcuminoids Tablets

Powdered Soy Isoflavones Extract

Soy Isoflavones Capsules

Soy Isoflavones Tablets

Turmeric

Powdered Turmeric

Powdered Turmeric Extract

USP MONOGRAPHS

Alfuzosin Hydrochloride

Bicalutamide Tablets

Bupivacaine Hydrochloride

Cabergoline

Cefdinir

Cefdinir Capsules

Fenofibrate Capsules

Flavoxate Hydrochloride

Flavoxate Hydrochloride Tablets

Formoterol Fumarate

Foscarnet Sodium

Granisetron Hydrochloride

Lisinopril and Hydrochlorothiazide Tablets

Mirtazapine Orally Disintegrating Tablets

Pantoprazole Sodium

Pantoprazole Sodium Delayed-Release Tablets

Piperazine Adipate

Piperazine Dihydrochloride

Piperazine Phosphate

Potassium Bromide Oral Solution, Veterinary

Propofol Injectable Emulsion

Sodium Bromide Injection, Veterinary

Sodium Bromide Oral Solution, Veterinary

Tamsulosin Hydrochloride

ANNOTATED LIST

General Notices , Monographs , General Chapters , Reagents , and Tables Affected by Changes Appearing in USP 32

Page citations refer to the pages of USP 32. Note—In the table below , if a section is new or if a subsection is added to or deleted from an existing section , it is labeled as such in parentheses after the section or subsection name. Items on this list that appear without the designation “new,” “added,” or “deleted,” are items in which changes have been made to existing official text.

General Notices and Requirements

General Chapters

General Tests and Assays

general requirements for test and assays

《11》 USP Reference Standards

Other tests and assays

《381》 Elastomeric Closures for Injections

Introduction

Test Procedures

physical tests and determinations

《621》 Chromatography

Glossary of Symbols

《701》 Disintegration

Apparatus

General Information

〈1121〉 Nomenclature

General Nomenclature Forms

Reagents , Indicators , and Solutions

reagent specifications

Acetic Acid

8-Amino-6-methoxyquinoline (new)

α-Amylase

Bismuth Subnitrate (new)

Charcoal , Activated

Diethylene Glycol

Ferrous Sulfate

Hexylamine (new)

Naphthalene

4-(p-Nitrobenzyl)pyridine

Phloxine B (new)

Salicylaldehyde

Sodium Phosphite Pentahydrate (new)

Tetrahexylammonium Hydrogen Sulfate (new)

Tetrahydro-2-furancarboxylic Acid

Triethylamine Phosphate (new)

volumetric solutions

Bismuth Nitrate , 0.01 M

chromatographic reagents

L46

L63

L67

Reference Tables

container specifications for capsules and tablets

Arginine Capsules

Arginine Tablets

Bicalutamide Tablets

Cefdinir Capsules

Curcuminoids Capsules

Curcuminoids Tablets

Fenofibrate Capsules

Flavoxate Hydrochloride Tablets

Lisinopril and Hydrochlorothiazide Tablets

Mirtazapine Orally Disintegrating Tablets

Pantoprazole Sodium Delayed-Release Tablets

Soy Isoflavones Capsules

Soy Isoflavones Tablets

description and relative solubility of usp and nf articles

rAlbumin Human

Alfuzosin Hydrochloride

Cabergoline

Cefdinir

Corn Syrup

Diethylstilbestrol Diphosphate

Diethylstilbestrol Diphosphate Injection

Erythorbic Acid

Eucatropine Hydrochloride

Flavoxate Hydrochloride

Formoterol Fumarate Dihydrate

Foscarnet Sodium

Granisetron Hydrochloride

Lecithin

Pantoprazole Sodium

Piperazine Adipate

Piperazine Dihydrochloride

Piperazine Phosphate

Tamsulosin Hydrochloride

Vancomycin Hydrochloride

Sterile Vancomycin Hydrochloride

Monographs (Dietary Supplements)

Arginine Capsules (new)

Arginine Tablets (new)

Curcuminoids (new)

Curcuminoids Capsules (new)

Curcuminoids Tablets (new)

Powdered Soy Isoflavones Extract (new)

Soy Isoflavones Capsules (new)

Soy Isoflavones Tablets (new)

Turmeric (new)

Powdered Turmeric (new)

Powdered Turmeric Extract (new)

Monographs (USP 32)

Albendazole

Assay

Alendronate Sodium Tablets

Labeling

Dissolution

test 1

test 2 (added)

Alfuzosin Hydrochloride (new)

Allopurinol

Related compounds (subsections Allopurinol relatedcompound F solution and Standard stock solution)

Limit of hydrazine (added)

Aminophylline

Chemical information

Bicalutamide Tablets (new)

Bupivacaine Hydrochloride

Chemical information

Cabergoline (new)

Calcitonin Salmon

Microbial limits

Cefdinir (new)

Cefdinir Capsules (new)

Cefdinir for Oral Suspension (new)

Cefotetan Disodium

Water

Cefotetan for Injection

Water (added)

Other requirements

Chloroquine

Assay

Diclofenac Potassium

Identification (test B)

Diclofenac Potassium Tablets

Dissolution (subsection Tolerances)

Loss on drying (deleted)

Limit of potassium (deleted)

Related compounds (subsections Standard solution andProcedure)

Assay (subsections Standard preparation and Procedure)

Didanosine

USP Reference standards

Related compounds (subsections Standard stock solution C,Standard solution , System suitability solution, andChromatographic system)

Diethylstilbestrol Diphosphate (deleted)

Diethylstilbestrol Diphosphate Injection (deleted)

Dimethyl Sulfoxide

Definition

Congealing temperature (deleted)

Substances darkened by potassium hydroxide (deleted)

Limit of dimethyl sulfone (deleted)

Limit of nonvolatile residue

Related compounds (added)

Assay (added)

Dipivefrin Hydrochloride

Assay (subsections Assay preparation and Procedure)

Disopyramide Phosphate

Assay

Dronabinol

Packaging and storage

Related compounds (subsections Mobile phase , Systemsuitability solution , and Standard preparation , Sensitivitysolution , Chromatographic system, and Procedure)

Assay (subsection Chromatographic system)

Dyclonine Hydrochloride

Chemical information

Epinephrine

Assay

Estradiol

Chemical information

Labeling (added)

Eucatropine Hydrochloride (deleted)

Eucatropine Hydrochloride Ophthalmic Solution (deleted)

Fenofibrate Capsules (new)

Fexofenadine Hydrochloride and PseudoephedrineHydrochloride Extended-Release Tablets

Labeling (added)

Identification (test C)

Dissolution

test 1

test 2

Related compounds (subsection Procedure)

Assay (subsections Related compounds preparation , Standardstock preparation , Assay stock preparation , Assaypreparation , Chromatographic system, and Procedure)

Flavoxate Hydrochloride (new)

Flavoxate Hydrochloride Tablets (new)

Fluconazole

Related compounds

Fludeoxyglucose F 18 Injection

Chemical purity

limit of 2-chloro-2-deoxy-d-glucose (subsection Procedure)

Formoterol Fumarate (new)

Foscarnet Sodium (new)

Granisetron Hydrochloride (new)

Heparin Calcium

Definition

USP Reference standards

Identification

Heparin Sodium

Definition

USP Reference standards

Identification

Indium In 111 Chloride Solution

Radiochemical purity

Iopamidol

Chemical structure

USP Reference standards

Identification (test C)

Related compounds

Iopamidol Injection

Assay (subsections Solution A , Solution B , Mobile phase,Resolution solution, and Chromatographic system)

Isopropyl Alcohol

USP Reference standards

Ivermectin Tablets

Dissolution (added)

Levalbuterol Hydrochloride

Related compounds (added)

Levalbuterol Inhalation Solution

Color (added)

Related compounds (added)

Levothyroxine Sodium Tablets

Definition

Lidocaine and Prilocaine Cream

Related compounds (subsection Chromatographic system)

Lisinopril and Hydrochlorothiazide Tablets (new)

Meclizine Hydrochloride

Chromatographic purity (subsections Chromatographic systemand Procedure)

Meclizine Hydrochloride Tablets

Related comopunds (added)

Assay

Meloxicam Tablets

Dissolution (added)

Meradimate

Assay (subsection Chromatographic system)

Methoxsalen Capsules

Assay (subsections Standard preparation , Assay preparation , Chromatographic system, and Procedure)

Methylprednisolone

Chromatographic purity (subsection Procedure)

Assay (subsection Procedure)

Mirtazapine Orally Disintegrating Tablets (new)

Mupirocin Calcium

Identification (test B)

Related compounds (subsections Chromatographic system andProcedure)

Assay (subsection Procedure)

Naproxen Delayed-Release Tablets

Identification (test A)

Dissolution

Norethindrone and Ethinyl Estradiol Tablets

Identification

Norethindrone Acetate and Ethinyl Estradiol Tablets

Dissolution (subsection Chromatographic system)

Nystatin Oral Suspension

Uniformity of dosage units

Pantoprazole Sodium (new)

Pantoprazole Sodium Delayed-Release Tablets (new)

Pentazocine and Acetaminophen Tablets

Assay for pentazocine (subsection Assay preparation)

Assay for acetaminophen (subsections Standard preparationand Assay preparation)

Piperazine

USP Reference standards (added)

Identification

Primary amines and ammonia (deleted)

Chromatographic purity (added)

Piperazine Adipate (new)

Piperazine Citrate

- USP Reference standards (added)
- Identification
- Primary amines and ammonia (deleted)
- Chromatographic purity (added)
- Assay

Piperazine Dihydrochloride (new)

Piperazine Phosphate (new)

Polyethylene Glycol 3350 and Electrolytes for OralSolution

- USP Reference standards (added)
- Identification (test A)
- Assay for potassium and sodium (subsection Chromatographicsystem)
- Assay for polyethylene glycol 3350 (subsection Standardpreparation)

Polyvinyl Alcohol

- Definition
- Packaging and storage
- Labeling (added)
- USP Reference standards (added)
- Identification (added)
- Viscosity
- Residue on ignition
- Heavy metals (added)
- Acid value (added)
- Water-insoluble matter
- Limit of methanol (methyl alchol) and methyl acetate (added)

Potassium Bromide Oral Solution , Veterinary (new)

Prednisolone Sodium Phosphate

- Definition
- Free prednisolone (deleted)
- Related compounds (added)
- Assay

Propofol Injectable Emulsion (new)

Propoxycaine and Procaine Hydrochlorides and Norepinephrine Bitartrate Injection

Assay for norepinephrine (subsection Procedure)

Pseudoephedrine Hydrochloride

Ordinary impurities (subsections Eluant and Visualization)

Salsalate Tablets

Assay (subsection Mobile phase , Diluent , Salsalate standardpreparation , Salicylic acid standard preparation,Resolution solution , and Chromatographic system)

Sodium Bromide Injection , Veterinary (new)

Sodium Bromide Oral Solution , Veterinary (new)

Tamsulosin Hydrochloride (new)

Torsemide

Water

Valproate Sodium Injection

Title

Definition

Admissions

Articles Admitted to NF 27 by Supplement

First Supplement (August 1, 2008)	
Hydrogenated Polydecene	Propylene Glycol Monocaprylate

Second Supplement (December 1, 2008)	
Dehydroacetic Acid	Propylene Glycol Dicaprylate/Dicaprate
Gamma Cyclodextrin	Pullulan
Hydrophobic Colloidal Silica	Stannous Chloride
Inositol	

Revisions Appearing in NF 27 That Were Not Included in NF 26 Including Supplements

[note—The articles included in this list are noted in the book with the following symbols ▲▲NF27. This applies to new articles as well as sections of existing items that have been revised.]

New Articles Appearing in NF 27	
Corn Syrup	Erythorbic Acid

ANNOTATED LIST

General Notices , Monographs , General Chapters , Reagents , and Tables Affected by

Changes Appearing in NF 27

Page citations refer to the pages of NF 27. Note—In the table below , if a section is new or if a subsection is added to or deleted from an existing section , it is labeled as such in parentheses after the section or subsection name. Items on this list that appear without the designation “new,” “added,” or “deleted,” are items in which changes have been made to existing official text.

General Notices and Requirements (deleted)

Excipients

Antimicrobial Preservative

Erythorbic Acid

Antioxidant

Erythorbic Acid

Suspending and/or Viscosity-increasing Agent

Corn Syrup

Sweetening Agent

Corn Syrup

Tablet Binder

Corn Syrup

Tablet and/or Capsule Diluent

Corn Syrup

Tonicity Agent

Corn Syrup

Vehicle

sterile

rAlbumin Human

Monographs (NF 27)

Acetone

USP Reference standards (added)

Identification (test A and B)

Water (subsections Chromatographic systemand Procedure)

Assay

rAlbumin Human (new)

Alfadex

USP Reference standards

Identification (test B)

Heavy metals

Reducing sugars (subsections Standard stock solution,Standard solution, and Procedure)

Related compounds (subsection Procedure

Assay (subsections Mobile phase , System suitabilitypreparation , Assay stock preparation,Chromatographic system, and Procedure)

Betadex

Chemical information

Packaging and storage

USP Reference standards

Identification (test C)

Microbial limits

pH (added)

Heavy metals

Reducing sugars

Light-absorbing impurities (added)

Related compounds (added)

Assay

Butylated Hydroxytoluene

USP Reference standards (added)

Identification

Related compounds (added)

Carbomer 934

Title change

Definition

Packaging and storage

Viscosity

Carbomer 934P

Title change

Definition

Packaging and storage

Viscosity

Carbomer 940

Title change

Definition

Packaging and storage

Viscosity

Carbomer 941

Title change

Definition

Packaging and storage

Viscosity

Carbomer Copolymer

Definition

Labeling

Viscosity

Limit of benzene (subsection Solvent solution)

Limit of acrylic acid (subsections Test solution andProcedure)

Carbomer Homopolymer

Definition

Labeling

Viscosity

Residue on ignition

Limit of benzene (subsection Procedure)

Limit of acrylic acid (subsection Procedure)

Carbomer Interpolymer

Definition

Labeling

Viscosity

Limit of benzene (subsection Procedure)

Limit of acrylic acid (subsection Procedure)

Corn Syrup (new)

Erythorbic Acid (new)

Ethyl Acrylate and Methyl Methacrylate Copolymer Dispersion

Identification

Limit of monomers (subsections Standard solutionand Procedure)

Liquid Glucose

Chemical information

Packaging and storage

Labeling (added)

USP Reference standards (added)

Identification

Assay for reducing sugars (dextrose equivalent)(added)

Glyceryl Monooleate

Chemical information

USP Reference standards

Identification (test A)

Saponification value

Lecithin

Chemical information

Packaging and storage

Labeling (added)

USP Reference standards (added)

Identification (added)

Acid value

Peroxide value (added)

Hexane-insoluble matter

Lead

Heavy metals

Content of acetone-insoluble matter

Methyl Alcohol

USP Reference standards (added)

Identification

Assay

Propylene Glycol Monolaurate

USP Reference standards

Identification (test A)

In the following reference table, the grouping of excipients by functional category is intended to summarize the most typically identified purpose that these excipients serve in drug product formulations. The list of substances included in each category is not comprehensive. The statement of category is intended neither to limit in any way the choice or use of the substance nor to indicate that it has no other utility.

Acidifying Agent

Acetic Acid
Acetic Acid, Glacial
Citric Acid, Anhydrous
Citric Acid Monohydrate
Fumaric Acid
Hydrochloric Acid
Hydrochloric Acid, Diluted
Malic Acid
Nitric Acid
Phosphoric Acid
Phosphoric Acid, Diluted
Propionic Acid
Sulfuric Acid
Tartaric Acid

Aerosol Propellant

Butane
Dichlorodifluoromethane
Dichlorotetrafluoroethane
Isobutane
Propane
Trichloromonofluoromethane

Air Displacement

Carbon Dioxide
Nitrogen

Alcohol Denaturant

Denatonium Benzoate
Methyl Isobutyl Ketone
Sucrose Octaacetate

Alkalizing Agent

Ammonia Solution, Strong
Ammonium Carbonate
Diethanolamine
Potassium Hydroxide
Sodium Bicarbonate
Sodium Borate
Sodium Carbonate
Sodium Hydroxide
Trolamine

Anticaking Agent (See Glidant)

Antifoaming Agent

Dimethicone

Myristic Acid
Palmitic Acid
Simethicone

Change to read:

Antimicrobial Preservative

Benzalkonium Chloride
Benzalkonium Chloride Solution
Benzethonium Chloride
Benzoic Acid
Benzyl Alcohol
Butylparaben
Cetrimonium Bromide
Cetylpyridinium Chloride
Chlorobutanol
Chlorocresol
Cresol
Dehydroacetic Acid
▲ Erythorbic Acid▲NF27
Ethylparaben
Methylparaben
Methylparaben Sodium
Phenol
Phenoxyethanol
Phenylethyl Alcohol
Phenylmercuric Acetate
Phenylmercuric Nitrate
Potassium Benzoate
Potassium Sorbate
Propylparaben
Propylparaben Sodium
Sodium Benzoate
Sodium Dehydroacetate
Sodium Propionate
Sorbic Acid
Thimerosal
Thymol

Change to read:

Antioxidant

Ascorbic Acid
Ascorbyl Palmitate
Butylated Hydroxyanisole
Butylated Hydroxytoluene
Stannous Chloride
▲ Erythorbic Acid▲NF27
Hypophosphorous Acid
Monothioglycerol
Potassium Metabisulfite
Propyl Gallate
Sodium Bisulfite
Sodium Formaldehyde Sulfoxylate
Sodium Metabisulfite
Sodium Sulfite
Sodium Thiosulfate
Sulfur Dioxide
Tocopherol
Tocopherols Excipient

Buffering Agent

Acetic Acid
Adipic Acid
Ammonium Carbonate
Ammonium Phosphate
Boric Acid
Citric Acid, Anhydrous
Citric Acid Monohydrate
Lactic Acid
Phosphoric Acid
Potassium Citrate
Potassium Metaphosphate
Potassium Phosphate, Dibasic
Potassium Phosphate, Monobasic
Sodium Acetate
Sodium Citrate
Sodium Lactate Solution

Sodium Phosphate, Dibasic
Sodium Phosphate, Monobasic
Succinic Acid

Bulking Agent for Freeze-Drying

Creatinine
Mannitol
Polydextrose
Pullulan

Capsule Lubricant (See Tablet and/or Capsule Lubricant)

Chelating Agent

Edetate Calcium Disodium
Edetate Disodium
Edetic Acid

Coating Agent

Amino Methacrylate Copolymer
Ammonio Methacrylate Copolymer
Ammonio Methacrylate Copolymer Dispersion
Carboxymethylcellulose, Sodium
Cellaburate
Cellacefate (formerly Cellulose Acetate Phthalate)
Cellulose Acetate
Cellulose Acetate Phthalate (see Cellacefate)
Coconut Oil
Copovidone
Corn Syrup Solids
Ethyl Acrylate and Methyl Methacrylate Copolymer Dispersion
Ethylcellulose
Ethylcellulose Aqueous Dispersion
Gelatin
Glaze, Pharmaceutical
Hydroxypropyl Cellulose

Hydroxypropyl Methylcellulose (see Hypromellose)
Hydroxypropyl Methylcellulose Phthalate (see Hypromellose Phthalate)
Hypromellose (formerly Hydroxypropyl Methylcellulose)
Hypromellose Acetate Succinate
Hypromellose Phthalate (formerly HydroxypropylMethylcellulose Phthalate)
Maltodextrin
Methacrylic Acid Copolymer
Methacrylic Acid Copolymer Dispersion
Methylcellulose
Palm Kernel Oil
Polyethylene Glycol
Polyvinyl Acetate Phthalate
Pullulan
Fully Hydrogenated Rapeseed Oil
Superglycerinated Fully Hydrogenated Rapeseed Oil
Shellac
Starch, Pregelatinized Modified
Sucrose
Titanium Dioxide
Wax, Carnauba
Wax, Microcrystalline
Zein

Color

Caramel
Ferric Oxide, red, yellow, or blends

Complexing Agent

Edetate Calcium Disodium
Edetate Disodium
Edetic Acid
Oxyquinoline Sulfate

Desiccant

Calcium Chloride
Calcium Sulfate

Silicon Dioxide

Emollient

Alkyl (C12-15) Benzoate
Hydrogenated Soybean Oil
Hydrogenated Polydecene
Oleyl Oleate

Emulsifying and/or Solubilizing Agent

Acacia
Carbomer Copolymer
Carbomer Interpolymer
Cholesterol
Stannous Chloride
Coconut Oil
Diethanolamine (Adjunct)
Diethylene Glycol Stearates
Ethylene Glycol Stearates
Gamma Cyclodextrin
Glyceryl Distearate
Glyceryl Monolinoleate
Glyceryl Monooleate
Glyceryl Monostearate
Lanolin Alcohols
Lecithin
Mono- and Di-glycerides
Monoethanolamine (Adjunct)
Oleic Acid (Adjunct)
Oleyl Alcohol (Stabilizer)
Oleyl Oleate
Palm Kernel Oil
Poloxamer
Polyoxyethylene 50 Stearate
Polyoxyl 10 Oleyl Ether
Polyoxyl 20 Cetostearyl Ether
Polyoxyl 35 Castor Oil
Polyoxyl 40 Hydrogenated Castor Oil

Polyoxyl 40 Stearate
Polyoxyl Lauryl Ether
Polyoxyl Stearyl Ether
Polysorbate 20
Polysorbate 40
Polysorbate 60
Polysorbate 80
Propylene Glycol Dicaprylate/Dicaprate
Propylene Glycol Monocaprylate
Propylene Glycol Monostearate
Superglycerinated Fully Hydrogenated Rapeseed Oil
Sodium Cetostearyl Sulfate
Sodium Lauryl Sulfate
Sodium Stearate
Sorbitan Monolaurate
Sorbitan Monooleate
Sorbitan Monopalmitate
Sorbitan Monostearate
Sorbitan Sesquioleate
Sorbitan Trioleate
Stearic Acid
Trolamine
Wax, Emulsifying

Filtering Aid

Cellulose, Powdered
Siliceous Earth, Purified

Flavors and Perfumes

Almond Oil
Anethole
Benzaldehyde
Ethyl Acetate
Ethyl Vanillin
Lactitol
Maltol
Menthol

Methyl Salicylate
Monosodium Glutamate
Peppermint
Peppermint Oil
Peppermint Spirit
Rose Oil
Rose Water, Stronger
Thymol
Vanillin

Glidant and/or Anticaking Agent

Calcium Silicate
Magnesium Silicate
Hydrophobic Colloidal Silica
Silicon Dioxide, Colloidal
Talc

Humectant

Corn Syrup Solids
Erythritol
Glycerin
Hexylene Glycol
Inositol
Maltitol
Polydextrose
Propylene Glycol
Sorbitol
Sorbitol Sorbitan Solution
Tagatose

Ointment Base

Caprylocaproyl Polyoxylglycerides
Diethylene Glycol Monoethyl Ether
Hydrogenated Polydecene
Lanolin
Lauroyl Polyoxylglycerides

Linoleoyl Polyoxylglycerides
Ointment, Hydrophilic
Ointment, White
Ointment, Yellow
Oleoyl Polyoxylglycerides
Polyethylene Glycol Monomethyl Ether
Petrolatum
Petrolatum, Hydrophilic
Petrolatum, White
Rose Water Ointment
Squalane
Stearoyl Polyoxylglycerides
Vegetable Oil, Hydrogenated, Type II

Plasticizer

Acetyltributyl Citrate
Acetyltriethyl Citrate
Castor Oil
Diacetylated Monoglycerides
Dibutyl Sebacate
Diethyl Phthalate
Glycerin
Polyethylene Glycol
Polyethylene Glycol Monomethyl Ether
Propylene Glycol
Pullulan
Sorbitol Sorbitan Solution
Triacetin
Tributyl Citrate
Triethyl Citrate

Polymer Membrane

Amino Methacrylate Copolymer
Ammonio Methacrylate Copolymer
Ammonio Methacrylate Copolymer Dispersion
Cellaburate
Cellulose Acetate

Ethyl Acrylate and Methyl Methacrylate Copolymer Dispersion
Pullulan

Sequestering Agent

Beta Cyclodextrin (see Betadex)
Betadex (formerly Beta Cyclodextrin)
Hydroxypropyl Betadex
Gamma Cyclodextrin
Pullulan
Sodium Tartrate

Solvent

Acetone
Alcohol
Alcohol, Diluted
Amylene Hydrate
Benzyl Benzoate
Butyl Alcohol
Canola Oil
Caprylocaproyl Polyoxylglycerides
Corn Oil
Cottonseed Oil
Diethylene Glycol Monoethyl Ether
Ethyl Acetate
Glycerin
Hexylene Glycol
Hydrogenated Polydecene
Isopropyl Alcohol
Lauroyl Polyoxylglycerides
Linoleoyl Polyoxylglycerides
Methyl Alcohol
Methylene Chloride
Methyl Isobutyl Ketone
Mineral Oil
Oleoyl Polyoxylglycerides
Peanut Oil
Polyethylene Glycol

Polyethylene Glycol Monomethyl Ether
Propylene Glycol
Sesame Oil
Stearoyl Polyoxylglycerides
Water for Injection
Water for Injection, Sterile
Water for Irrigation, Sterile
Water, Purified

Sorbent

Cellulose, Powdered
Charcoal, Activated
Siliceous Earth, Purified

Sorbent, Carbon Dioxide

Barium Hydroxide Lime
Soda Lime

Stiffening Agent

Castor Oil, Hydrogenated
Cetostearyl Alcohol
Cetyl Alcohol
Cetyl Esters Wax
Cetyl Palmitate
Hard Fat
Paraffin
Synthetic Paraffin
Fully Hydrogenated Rapeseed Oil
Superglycerinated Fully Hydrogenated Rapeseed Oil
Stearyl Alcohol
Wax, Emulsifying
Wax, White
Wax, Yellow

Suppository Base

Cocoa Butter
Hard Fat
Polyethylene Glycol

Change to read:

Suspending and/or Viscosity-increasing Agent

Acacia
Agar
Alamic Acid
Alginic Acid
Aluminum Monostearate
Attapulgite, Activated
Attapulgite, Colloidal Activated
Bentonite
Bentonite, Purified
Bentonite Magma
Carbomer 910
Carbomer 934
Carbomer 934P
Carbomer 940
Carbomer 941
Carbomer 1342
Carbomer Copolymer
Carbomer Homopolymer
Carbomer Interpolymer
Carboxymethylcellulose Calcium
Carboxymethylcellulose Sodium
Carboxymethylcellulose Sodium 12
Carrageenan
Cellulose, Microcrystalline, and CarboxymethylcelluloseSodium
▲Corn Syrup▲NF27
Corn Syrup Solids
Dextrin
Gelatin
Gellan Gum
Guar Gum
Hydroxyethyl Cellulose
Hydroxypropyl Cellulose

Hydroxypropyl Methylcellulose (see Hypromellose)
Hypromellose (formerly Hydroxypropyl Methylcellulose)
Magnesium Aluminum Silicate
Maltodextrin
Methylcellulose
Pectin
Polyethylene Oxide
Polyvinyl Alcohol
Povidone
Propylene Glycol Alginate
Pullulan
Hydrophobic Colloidal Silica
Silicon Dioxide
Silicon Dioxide, Colloidal
Sodium Alginate
Starch, Corn
Starch, Potato
Starch, Tapioca
Starch, Wheat
Tragacanth
Xanthan Gum

Change to read:

Sweetening Agent

Acesulfame Potassium
Aspartame
Aspartame Acesulfame
▲Corn Syrup▲NF27
Corn Syrup Solids
High Fructose Corn Syrup
Dextrates
Dextrose
Dextrose Excipient
Erythritol
Fructose
Galactose
Maltitol
Maltose
Mannitol

Saccharin
Saccharin Calcium
Saccharin Sodium
Sorbitol
Sorbitol Solution
Sucralose
Sucrose
Sugar, Compressible
Sugar, Confectioner's
Syrup
Tagatose

Change to read:

Tablet Binder

Acacia
Alginic Acid
Amino Methacrylate Copolymer
Ammonio Methacrylate Copolymer
Ammonio Methacrylate Copolymer Dispersion
Carbomer Copolymer
Carbomer Homopolymer
Carbomer Interpolymer
Carboxymethylcellulose Sodium
Cellulose, Microcrystalline
Copovidone
▲Corn Syrup▲NF27
Corn Syrup Solids
Dextrin
Ethyl Acrylate and Methyl Methacrylate Copolymer Dispersion
Ethylcellulose
Gelatin
Glucose, Liquid
Guar Gum
Low-Substituted Hydroxypropyl Cellulose
Hydroxypropyl Methylcellulose (see Hypromellose)
Hypromellose (formerly Hydroxypropyl Methylcellulose)
Hypromellose Acetate Succinate
Maltodextrin
Maltose

Methylcellulose
Polyethylene Oxide
Povidone
Pullulan
Starch, Corn
Starch, Potato
Starch, Pregelatinized
Starch, Pregelatinized Modified
Starch, Tapioca
Starch, Wheat
Syrup

Change to read:

Tablet and/or Capsule Diluent

Calcium Carbonate
Calcium Phosphate, Dibasic
Calcium Phosphate, Tribasic
Calcium Sulfate
Cellulose, Microcrystalline
Cellulose, Powdered
▲Corn Syrup▲NF27
Corn Syrup Solids
Dextrates
Dextrin
Dextrose Excipient
Fructose
Kaolin
Lactitol
Lactose, Anhydrous
Lactose, Monohydrate
Maltitol
Maltodextrin
Maltose
Mannitol
Propylene Glycol Monocaprylate
Pullulan
Sorbitol
Starch
Starch, Corn

Starch, Potato
Starch, Pregelatinized
Starch, Pregelatinized Modified
Starch, Tapioca
Starch, Wheat
Sucrose
Sugar, Compressible
Sugar, Confectioner's

Tablet Disintegrant

Alginic Acid
Cellulose, Microcrystalline
Croscarmellose Sodium
Crospovidone
Low-Substituted Hydroxypropyl Cellulose
Maltose
Polacrilin Potassium
Pullulan
Sodium Starch Glycolate
Starch
Starch, Corn
Starch, Potato
Starch, Pregelatinized
Starch, Pregelatinized Modified
Starch, Tapioca
Starch, Wheat

Tablet and/or Capsule Lubricant

Calcium Stearate
Glyceryl Behenate
Magnesium Stearate
Mineral Oil, Light
Polyethylene Glycol
Polyoxyl 10 Oleyl Ether
Polyoxyl 20 Cetostearyl Ether
Polyoxyl 35 Castor Oil
Polyoxyl 40 Hydrogenated Castor Oil

Polyoxyl 40 Stearate
Polysorbate 20
Polysorbate 40
Polysorbate 60
Polysorbate 80
Sodium Lauryl Sulfate
Sodium Stearyl Fumarate
Sorbitan Monolaurate
Sorbitan Monooleate
Sorbitan Monopalmitate
Sorbitan Monostearate
Sorbitan Sesquioleate
Sorbitan Trioleate
Starch
Stearic Acid
Stearic Acid, Purified
Talc
Vegetable Oil, Hydrogenated, Type I
Zinc Stearate

Change to read:

Tonicity Agent

▲Corn Syrup▲NF27
Corn Syrup Solids
Dextrose
Glycerin
Mannitol
Potassium Chloride
Sodium Chloride

Change to read:

Vehicle

FLAVORED AND/OR SWEETENED

Aromatic Elixir
Benzaldehyde Elixir, Compound
Corn Syrup Solids
Dextrose

Peppermint Water
Sorbitol Solution
Syrup

OLEAGINOUS

Alkyl (C12-15) Benzoate
Almond Oil
Canola Oil
Corn Oil
Cottonseed Oil
Ethyl Oleate
Hydrogenated Polydecene
Isopropyl Myristate
Isopropyl Palmitate
Mineral Oil
Mineral Oil, Light
Octyldodecanol
Olive Oil
Peanut Oil
Safflower Oil
Sesame Oil
Soybean Oil
Squalane

SOLID CARRIER

Corn Syrup Solids
Propylene Glycol Dicaprylate/Dicaprate
Propylene Glycol Monocaprylate
Sugar Spheres

STERILE

▲rAlbumin Human▲NF27
Sodium Chloride Injection, Bacteriostatic
Water for Injection, Bacteriostatic

Viscosity-Increasing (See Suspending Agent)

Water Repelling Agent

Cyclomethicone
Dimethicone
Simethicone

Wetting and/or Solubilizing Agent

Benzalkonium Chloride
Benzethonium Chloride
Cetylpyridinium Chloride
Docusate Sodium
Nonoxynol 9
Octoxynol 9
Poloxamer
Polyoxyl 10 Oleyl Ether
Polyoxyl 20 Cetostearyl Ether
Polyoxyl 35 Castor Oil
Polyoxyl 40 Hydrogenated Castor Oil
Polyoxyl 40 Stearate
Polysorbate 20
Polysorbate 40
Polysorbate 60
Polysorbate 80
Pullulan
Sodium Lauryl Sulfate
Sorbitan Monolaurate
Sorbitan Monooleate
Sorbitan Monopalmitate
Sorbitan Monostearate
Sorbitan Sesquioleate
Sorbitan Trioleate
Tyloxapol