

# New concept proposal

## Pharmaceutical Dose Form

<b>Author</b>	Kristin Gnodtke	<b>Date last updated</b>	18.05.2022
<b>Project</b>	-	<b>Contact person</b>	-
<b>Dataset release</b>	2022.1	<b>Consulted expert</b>	-

### 1 Rationale

The pharmaceutical dose form, such as solution or coated capsule is an important property of a medication. It influences the speed of absorption and the onset of drug action. In the current release of the SPHN Dataset the pharmaceutical dose form is represented with the term “galenic” in the concepts *Durg Administration Event* and the *Drug Prescription*. However, recent development in Identification for Medicinal Products (IDMP) has revealed the need for differentiating between manufactured dose form and administrable dose form which are both of type pharmaceutical dose form. As according to the semantic strategy a meaning should be represented only once in the SPHN Dataset, the *Pharmaceutical Dose Form* concept should be added and thus made available for resues in the different contexts.

### 2 Comparison to other standards/data models

#### 2.1 UMLS

In UMLS, there are several definitions for dosage forms with the concept unique identifier (CUI) C0013058:

Completed forms of the pharmaceutical preparation in which prescribed doses of medication are included. They are designed to resist action by gastric fluids, prevent vomiting and nausea, reduce or alleviate the undesirable taste and smells associated with oral administration, achieve a high concentration of drug at target site, or produce a delayed or long-acting drug effect. **(MSH)**

The form in which active and/or inert ingredient(s) are physically presented. **(NCI)**

Physical characteristics of a drug product, (e.g., tablet, capsule, or solution) that contains a drug substance, generally-but not necessarily-in association with one or more other ingredients. [21 CFR 314.3 and after IDMP]. See also drug product. **(NCI)**

The pharmaceutical dosage form of the drug administered. **(NCI)**

Forms in which chemical products can be manufactured or administered. **(CSP)**

## 2.2 SNOMED CT

The SNOMED CT concept 736542009 [Pharmaceutical dose form (dose form)] has 328 children. SNOMED International is developing a map from EDQM codes to SNOMED codes for pharmaceutical dose form for the purpose of semantic interoperability between regulatory and healthcare systems and for population based analytics.

## 2.3 EDQM

The European Directorate for the Quality of Medicines & Healthcare (EDQM) publishes the EDQM codes for pharmaceutical dose forms under the Object Identifier (OID) 0.4.0.127.0.16.1.1.2.2.

Definition of Pharmaceutical Dose form published by EDQM: “Physical manifestation of a product that contains the active ingredient(s) and/or inactive ingredient(s) that are intended to be delivered to the patient”. Source: Standard Terms: Introduction and Guidance for Use Version 2.1.3 – 16 November 2018.

Example of an EDQM code:

DETAILS	CHARACTERISTICS	TRANSLATIONS	SUMMARY SHEETS
<b>Concept Code</b>	10701000		
<b>Term</b>	Ear cream		
<b>Definition</b>	Semi-solid single-dose or multidose preparation consisting of a cream intended for application to the external auditory meatus, if necessary by means of a tampon impregnated with the preparation.		
<b>Concept Class</b>	PDF		
<b>Ph. Eur. Monograph</b>	0652		
<b>Domain</b>	Human and Veterinary		
<b>Concept Status</b>	Current		
<b>Version Number</b>	2		
<b>Version creation date</b>	2016-03-30 09:11:35		
<b>Modification made</b>	Definition harmonised.		
<b>Language</b>	English		
<b>Expanded code</b>	PDF-10701000-EN-GB		
<b>Concept Creation Date</b>	2006-03-14 00:00:00		

### 3 Concept information

Concept name	Description	Type	Standard	Value set	Meaning binding SNOMED CT	Meaning binding LOINC
<b>Pharmaceutical Dose Form</b>	physical manifestation of a product that contains the active ingredient(s) and/or inactive ingredient(s) that are intended to be delivered to the patient				736542009  Pharmaceutical dose form (dose form)	
code	code, coding system and version used to define the pharmaceutical dose form	Code	SNOMED CT	child of : 736542009  Pharmaceutical dose form (dose form)		

### 4 Impact on the SPHN Dataset

The new *Pharmaceutical Dose Form* concept can be reused in the concept *Drug* (for manufactured dose form) and in the concepts *Drug Administration Event* and *Drug Prescription* (for administrable dose form).