

Medikation – Einsatz von ATC, IDMP und anderen Terminologien

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2017-09-18 Symposium: Medizinische Klassifikationen und Terminologien
– Bausteine für den Brückenbau mit Visionen
GMDS 2017



Anforderungen

ATC, etc.

IDMP

Aktualität

- ▶ Kerndatensatz der Medizininformatik-Initiative: Medikation an zweiter Stelle
- ▶ eRezept
- ▶ eGK

Relevanz

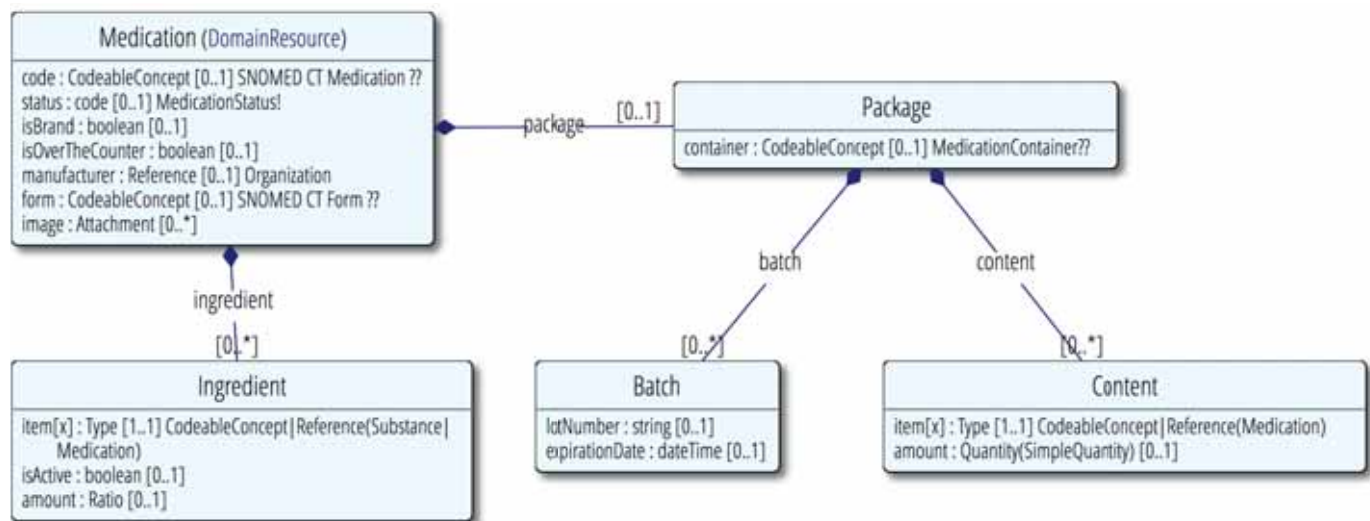
- ▶ klinische Medizin
- ▶ Pharmazie
 - ▶ Apotheken
 - ▶ Entwicklung, Zulassung und Produktion
- ▶ Sicherheit, Pharmakovigilanz
 - ▶ Nebenwirkungen
 - ▶ Kontraindikationen
 - ▶ Wechselwirkungen

HL7 FHIR Release 3 Module Medications

- ▶ Medication
- ▶ MedicationStatement
- ▶ MedicationRequest
- ▶ MedicationDispense
- ▶ MedicationAdministration
- ▶ Immunization
- ▶ ImmunizationRecommendation

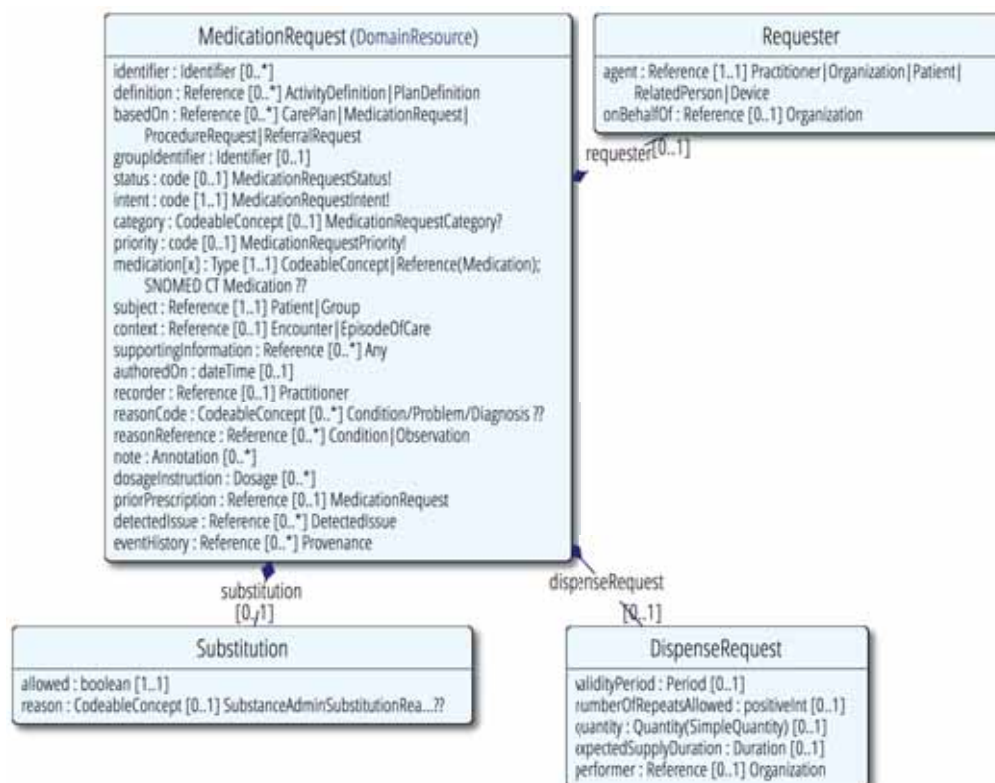
<https://www.hl7.org/fhir/medications-module.html>

HL7 FHIR Release 3 Resource Medication



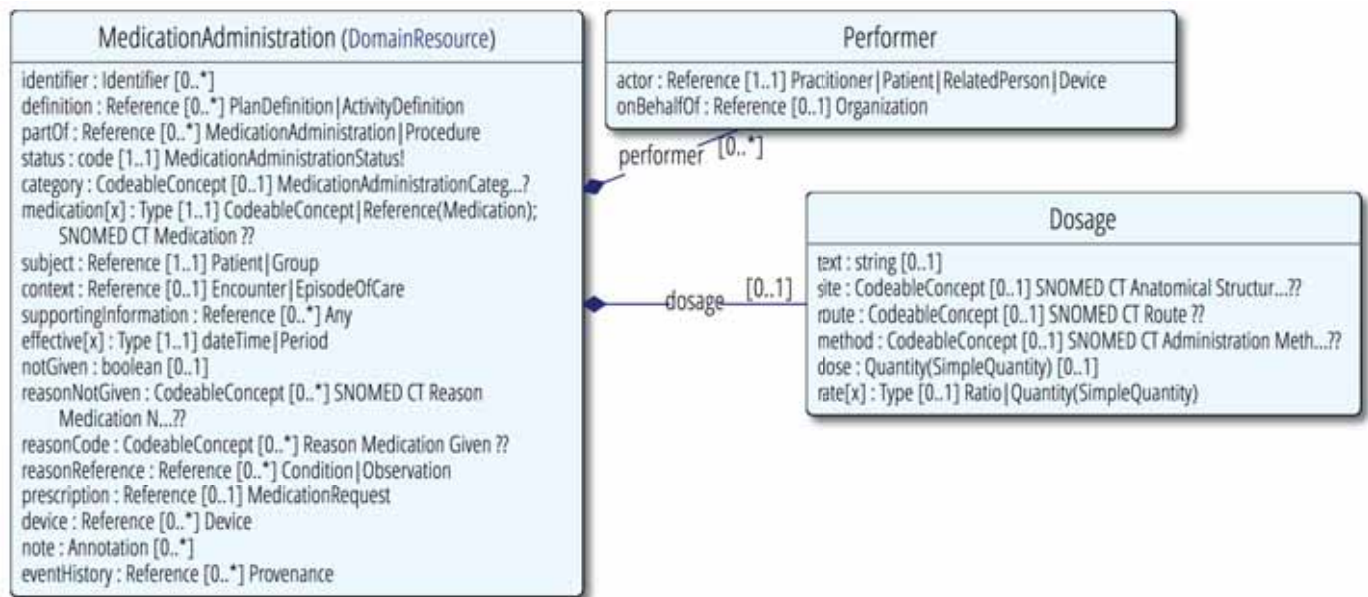
<https://www.hl7.org/fhir/medication.html>

HL7 FHIR Release 3 Resource Medication Request



<https://www.hl7.org/fhir/medicationrequest/.html>

HL7 FHIR Release 3 Resource Medication Administration



<https://www.hl7.org/fhir/medicationadministration.html>

Anforderungen an Terminologien/ Ontologien für Medikation (FHIR)

- ▶ Indikation
- ▶ Inhaltsstoffe, aktive Substanz(en), Wirkstoffe
- ▶ Dosierungen
- ▶ Darreichungsform, Applikation (Art, Weg und Methode)
- ▶ Handelsnamen
- ▶ Packungsgrößen
- ▶ Hersteller
- ▶ Aufbewahrungshinweise, Haltbarkeit
- ▶ Nebenwirkungen, Kontraindikationen, Wechselwirkungen

ATC

- ▶ Anatomical Therapeutic Chemical / Defined Daily Dose Classification ATC/ DDD
- ▶ 1976 European Pharmaceutical Market Research Association (EPHRA)
- ▶ 1990 Collaborating Centre for Drug Statistics der WHO
- ▶ 5 Hierarchie-Ebenen
 1. 14 Hauptgruppen nach Organen
 2. Therapiegruppen
 3. Therapieuntergruppen
 4. chemische Struktur
 5. chemische Substanz
- ▶ Klassifikation von Arzneimitteln nach Indikationen
 - ▶ ungeeignet zum Retrieval über Substanzen/ Substanzgruppen

ATC Beispiel

Aspirin (Acetylsalicylsäure):

- ▶ A Alimentäres System und Stoffwechsel, , , Andere Mittel zur oralen Lokalbehandlung: A01AD05
- ▶ B Blut und Blutbildende Organe, , , Thrombozytenaggregationshemmer: B01AC06
- ▶ N Nervensystem, , , Salicylsäure und Derivate: N02BA01
- ▶ zusätzlich in 8 verschiedenen Kombinationen

ATC/ DDD. Amtliche deutsche Fassung, 14. Version. DIMDI

Pharmazentralnummer (PZN)

- ▶ IFA GmbH: Informationsstelle für Arzneispezialitäten (Fertigarzneimittel)
 - ▶ Umrechnung in PPN: Pharmacy Product Number
- ▶ IFA-Datenbank mit Produkt-spezifischen Informationen
- ▶ ABDA: Bundesvereinigung Deutscher Apothekerverbände
 - ▶ ABDA-Datenbank (ABDATA von AVOXA)
 - ▶ Fertigarzneimittel
 - ▶ Pharmazeutische Stoffliste
 - ▶ Wirkstoffdossiers
 - ▶ Interaktionen

RxNorm

- ▶ normalized naming system for generic and branded drugs
- ▶ a tool for supporting semantic interoperation between drug terminologies and pharmacy knowledge base systems
- ▶ National Library of Medicine (NLM)
- ▶ frei Verfügbarkeit
- ▶ Integration von 16 Terminologien, u.a. ATC, MeSH, Micromedex, FDA Structured Product Labels, Snomed CT drug information

RxNorm über RxNav

U.S. National Library of Medicine

String : Aspirin

Aspirin [RxCUI = 1191]

RxNorm Graph RxNorm Properties NDC RxTerms NDF-RT Pill Images Class View Interaction View Status

Views: Classic, Simple, Table

Filters: H, V, S, Group, Form

Legend: MIN, Pack, Multi

IN/MIN	Ingredient	PIN	Precise Ingredient	BN	Brand Name
H R M S	Aspirin	S	ACETYLSALICYLATE SODIUM	H R M S	Aggrenox
H R M S	Acetaminophen / Aspirin			H R M S	Alka-Seltzer
H R M S	Acetaminophen / Aspirin / Caffeine			H R M S	Alka-Seltzer Morning Relief
H R M S	Acetaminophen / Aspirin / Caffeine / Calcium			H R M S	Alka-Seltzer PM

SCDC	Clinical Drug Component	SBD/CPCK	Branded Drug Component
V S	Aspirin 1 MG/MG	H R M S	Acetaminophen 110 MG / Aspirin 162 MG / Caffeine 32.4 MG / salicylamide 152 MG [Exaprin]
S	Aspirin 1.5 MG/ML	H R M S	Acetaminophen 115 MG / Aspirin 210 MG /
S	Aspirin 100 MG		
H R M S	Aspirin 1000 MG		

SCDG/CPCK	Clinical Drug or Pack	SBD/CPCK	Branded Drug or Pack
H R M S	12 HR Aspirin 25 MG / Dipyridamole 200 MG Extended Release Oral Capsule	H R M S	Aggrenox 25/200 12HR Extended Release Oral Capsule
H R M S	24 HR Aspirin 162.5 MG Extended Release Oral Capsule	H R M S	Anacin Aspirin Regimen 81 MG Oral Tablet
H R M S	Acetaminophen 110 MG / Aspirin 162 MG / Caffeine 32.4 MG / salicylamide 152 MG Oral Tablet	H R M S	APAP 110 MG / ASA 162 MG / Caffeine 32.4
H R M S	Acetaminophen 115 MG / Aspirin 210 MG / Caffeine 16 MG / salicylamide 65 MG Oral Tablet		

SCDG	Clinical Dose Form Group	DFG	Dose Form Group	SBDG	Branded Dose Form Group
H R M S	Acetaminophen / Aspirin / Caffeine / salicylamide Oral Product	H R M S	Chewable Product	H R M S	Aggrenox Oral Product
H R M S	Acetaminophen / Aspirin / Caffeine / salicylamide Pill	H R M S	Disintegrating Oral Product	H R M S	Aggrenox Pill
		H R M S	Granule Product	H	Alka-Seltzer Granule Product
		H R M S	Oral Liquid Product	H R M S	Alka-Seltzer Morning Relief Oral Product

RxNorm/ ATC über RxNav

U.S. National Library of Medicine

String : Aspirin

Aspirin [RxCUI = 1191]

RxNorm Graph RxNorm Properties NDC RxTerms NDF-RT Pill Images Class View Interaction View Status

Views: ATC, MESH, Drug, Disease, DF, CHEM, MoA, PK, PE

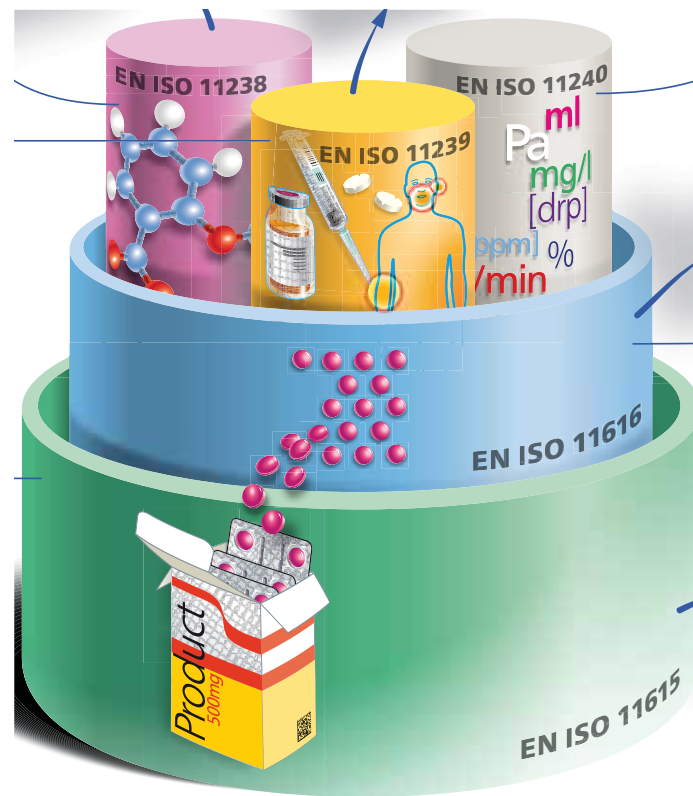
Hide Legend

```

    graph TD
        A[STOMATOLOGICAL PREPARATIONS] --> B[STOMATOLOGICAL PREPARATIONS]
        B --> C[Other agents for local oral treatment]
        D[BLOOD AND BLOOD FORMING ORGANS] --> E[B01]
        E --> F[ANTITHROMBOTIC AGENTS]
        F --> G[B01A]
        G --> H[ANTITHROMBOTIC AGENTS]
        H --> I[B01AC]
        I --> J[Platelet aggregation inhibitors excl. heparin]
        K[NERVOUS SYSTEM] --> L[ANALGESICS]
        L --> M[OTHER ANALGESICS AND ANTIPYRETICS]
        M --> N[Salicylic acid and derivatives]
        C --> O[acetylsalicylic acid]
        J --> O
        N --> O
    
```

Legend: Drug isa ATC Class isa ATC Class

IDMP – Identification of Medicinal Products

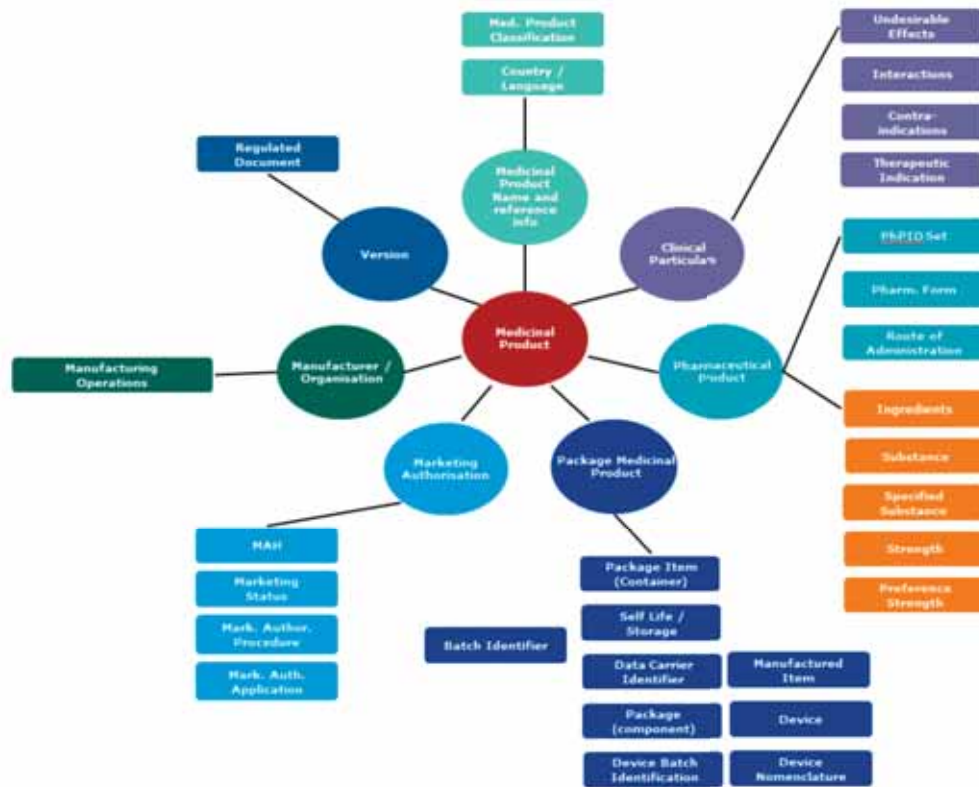


ISO TC 215, Working Group 6 (Pharmacy and Medicines Business), December 2014

IDMP

- ▶ ISO 11238: Data elements and structures for unique identification and exchange of regulated information on Substances (Substance ID)
- ▶ ISO 11239: Data elements and structures for unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging
- ▶ ISO 11240: Data elements and structures for unique identification and exchange of units of measurement (UCUM)
- ▶ ISO 11616: Data elements and structures for unique identification and exchange of regulated Pharmaceutical Product information (PhPID)
- ▶ ISO 11615: Data elements and structures for unique identification and exchange of regulated Medicinal Product information (MPID/PCID)

IDMP – Elements



Introduction to ISO Identification of Medicinal Products (IDMP), SPOR programme,

EMA / 700656 / 2015

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IDMP – ISO 11238 Substances

- ▶ GInAS: Global Ingredient Archival System (consistent with ISO 11238)
 - ▶ G-SRS software for registering and documenting
 - ▶ NCATS: National Center for Advancing Translational Science (NIH)

GInAS Example

G-SRS version 1.3.18 beta

Browse Substances | Structure Search | Sequence Search | Search [] [Q] [v]

ASPIRIN

Details | **Structure** | Moieties (1) | Names (76) | Codes (51) | Active Moieties (1) | Metabolites (3) | Impurities (11) | Relationships (12) | Notes (11) | References (73)

Chemical Details

RECORD STATUS: VALIDATED (UNII)
 VERSION: 1 | 2
 View audit details: []

Substance ID: R16C05Y76E []

Structure

Stereochemistry: ACHEIRAL
 Optical Activity: UNSPECIFIED
 Additional Stereochemistry: No
 Molecular Formula: C9H8O4
 Molecular Weight: 180.1574
 Defined Stereocenters: 0/0
 EZ Centers: 0
 Charge: 0
 StereoComments: []
 References: (2) []

[https://ginas.ncats.nih.gov/ginas/app/substances?q="aspirin"](https://ginas.ncats.nih.gov/ginas/app/substances?q=)

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GInAS Example

ASPIRIN

Details | Structure | Moieties (1) | Names (76) | **Codes (51)** | Active Moieties (1) | Metabolites (3) | Impurities (11) | Relationships (12) | Notes (11) | References (73)

C10BX02	WHO-ATC	PRIMARY	ATC CARDIOVASCULAR SYSTEM LIPID MODIFYING AGENTS LIPID MODIFYING AGENTS, COMBINATIONS HMG CoA reductase inhibitors, other combinations pravastatin and acetylsalicylic acid	(1)
CLOPIDOGREL/ACETYLSALICYLIC ACID (AUTHORIZED: MYOCARDIAL INFARCTION)	EMA ASSESSMENT REPORTS	PRIMARY	EMA EPAR DISEASES CARDIOVASCULAR DISEASES HEART DISEASES MYOCARDIAL ISCHEMIA MYOCARDIAL INFARCTION	(1)
50-78-2	CAS	PRIMARY		(1)
DUOCOVER (AUTHORIZED: ACUTE CORONARY SYNDROME)	EMA ASSESSMENT REPORTS	PRIMARY	EMA EPAR DISEASES CARDIOVASCULAR DISEASES HEART DISEASES MYOCARDIAL ISCHEMIA ACUTE CORONARY SYNDROME	(1)

[https://ginas.ncats.nih.gov/ginas/app/substances?q="aspirin"](https://ginas.ncats.nih.gov/ginas/app/substances?q=)

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IDMP – ISO 11239 Dose forms, Units of Presentation, Routes of Administration and Packaging

- ▶ SNOMED CT
- ▶ EDQM: European Directorate for the Quality of Medicines and HealthCare
 - ▶ Möglichkeit: Deutsche Therme als Interface Terminologie zu Snomed CT

Standard Terms der EDQM

The screenshot shows the EDQM Standard Terms website. The header includes the Council of Europe logo and the EDQM logo. The navigation menu has 'NEWS AND INFORMATION', 'BROWSE', and 'SEARCH'. A dropdown menu is open under 'BROWSE', listing the following categories:

- Pharmaceutical dose forms by Intended site
- Pharmaceutical dose forms by State of matter
- Combined pharmaceutical dose forms
- Combined terms
- Routes and methods of administration
- Packaging
- Combination packs
- Patient-friendly terms
- Units of presentation
- Mapped terms

The main content area includes a 'News and Information' section and a 'Guidance and...' section. The 'Guidance and...' section contains the following text:

The user guide and change request form are available at the following links:

- [Introduction and guidance](#)
 - [Version for national authorities](#)
- [Change request form \(v.1.0.0, 14/11/14\)](#)

Please note: the EDQM can also be accessed through the national competent authorities of ICH).

The lists of controlled vocabularies used to characterise pharmaceutical dose forms can also be downloaded by clicking on the following link:

- [Internal controlled vocabularies for pharmaceutical dose forms \(v.1.0.0, 14/11/14\)](#)

<https://standardterms.edqm.eu/#>

Standard Terms der EDQM: Dose forms

Current		Tablet	SY	A6mDP	Human and Veterinary
DETAILS	CHARACTERISTICS	TRANSLATIONS	LINKED TERMS	MAPPINGS	SUMMARY SHEETS
Concept Code	10219000				
Term	Tablet				
Definition	Solid single-dose uncoated preparation obtained by compressing uniform volumes of particulate solids or by other means such as extrusion or moulding. Tablets include single-layer tablets resulting from a single compression of particles and multi-layer tablets consisting of concentric or parallel layers obtained by successive compressions of particles of different composition. Tablets are intended for oral use to release active substance(s) in the gastrointestinal fluids by a rate depending essentially on the intrinsic properties of active substance(s) (conventional release).				
Concept Class	PDF				
Ph. Eur. Monograph	0478				
Domain	Human and Veterinary				
Concept Status	Current				
Version Number	1				
Version creation date	2006-03-14 00:00:00				
Language	English				
Expanded code	PDF-10219000-EN-GB				
Concept Creation Date	2006-03-14 00:00:00				

https://standardterms.edqm.eu/browse/get_concepts_by/ISI/PDF

Standard Terms der EDQM: Units of Presentation

DETAILS	TRANSLATIONS	SUMMARY SHEETS
Concept Code	15002000	
Term	Ampoule	
Definition	A unit of presentation used to represent the quantity of product that is found in a single ampoule container.	
Comment	For example, to describe the quantity of a solution for injection in a single ampoule: "contains 1 mL per ampoule".	
Concept Class	UOP	
Domain	Human and Veterinary	
Concept Status	Current	
Version Number	1	
Version creation date	2016-05-20 09:43:10	
Modification made	Coded Concept creation	
Language	English	
Expanded code	UOP-15002000-EN-GB	
Concept Creation Date	2016-05-20 09:43:10	

https://standardterms.edqm.eu/browse/get_concepts_by/ISI/UOP

IDMP – ISO 11238 Units

- ▶ UCUM: Unified Code for Units of Measure (based on ISO 80000)

EMA: EU phased regional IDPM implementation

- ▶ FROM: xEVMPD (Extended Eudravigilance Medicinal Product Dictionary)
- ▶ TO: ISO IDMP
- ▶ APPROACH: Master Data **SPOR**
 - ▶ Substance
 - ▶ Product
 - ▶ Organisations
 - ▶ Referentials
- ▶ June 2017: Registering super users, usage of the RMS (Referential Management Services)
- ▶ October 2017: Usage of OMS (Organisation Master Data) from October 2017

Schlussfolgerung

- ▶ Gefordert: Interoperabilität von Terminologien für Medikationsdaten
- ▶ Kandidaten
 - ▶ Snomed CT
 - ▶ ISO IDMP
- ▶ Integration von bestehende Terminologien