EDQM as a global terminology for Identification of Medicinal Products (IDMP) and UNICOM

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Acknowledgments and Disclosure

- The help of ISO/CEN Working Party on the revision of EN ISO 11239
  - Chris Jarvis

- The help from UNICOM Work Package 1
  (IDMP and Standard Development Organisations)
  - Christian Hay
  - Robert Stegwee

No conflict of interest to declare
Overview

► Our Background
► UNICOM, IDMP, and EDQM
   ▷ Short presentation of The UNICOM Project
   ▷ Dose Form as a key variable for Pharmaceutical Product Identification in IDMP
► Analysis of EDQM as a global terminology
   ▷ Analysis of strengths and limitations of the information on dose form
   ▷ Proposals for improvement
   ▷ Request to review a new spreadsheet
► Proposal for an ontology of dose form
   ▷ Analysis of unique combinations of values of characteristics
   ▷ Development of an ontology of dose form
► Dilemma for doseform and PHPID production
► Recapitulation our request
Our Background

► Work Package WP8 (IDMP and Clinical Care)

► GP and Clinical Pharmacologist
  ▶ Practice and research experience
  ▶ Training experience in medicine and pharmacy

► Belgian Independent Drug Information Centre
  ▶ Web information for health professionals
  ▶ The Authentic source of medicines (SAM Database)
  ▶ The Belgian ICT-Implementation of INN Prescribing

► Drug Utilisation Research
  ▶ ESAC project (European Surveillance of Antibiotic Consumption)
  ▶ Guidelines for Cross National Comparison of Drug Exposure

► Doctoral Thesis on drug information for patients in package inserts
A few words about UNICOM and IDMP
The UNICOM Project

What if

We would be able to recognise any medicinal product from anywhere in the world anywhere in the world.

That is the ambition of the 5 SO/CEN Standards
A large action program, from the EU Horizon programme,
▶ with a 20 MEURO Budget,
▶ 44 participating organisations,
▶ among which 11 National Competent Agency for marketing authorization of Medicinal Products and a number of eHealth Institutions
• [https://unicom-project.eu](https://unicom-project.eu)

Testimony of large institutional support for IDMP implementation
▶ Supported by ICH (International Council of Harmonisation)
▶ Supported by EMA, FDA
▶ Supported by a global Working Group (bringing together FDA, EMA, WHO_Uppsala Monitoring Centre for Pharmacovigilance)
▶ Supported by Horizon 20/20 through UNICOM
Perspective on future and history of IDMP implementation

Retrospective

Pharmaco-archeology

Legacy conversion of Over 500,000 products
Substance cleansing EDQM standardization Strength Normalisation

Prospective

IDMP-compliant industry submission to EMA/FDA of a few hundreds of new products per year
The role of Dose Form in IDMP identification of Products

Dose Form is a key element that determines the pharmaceutical product, together with substance and strength.

- Substance
  - Substance with the role of Precise Active Ingredient
  - Dose Form
    - Administrable Dose Form
  - Strength
    - Value of (reference) Strength
    - Unit of nominator and denominator (presentation or concentration)

Note: Substance with dose form and strength determine the effect of the medication.
Implementation of Global Pharmaceutical product (PhPID) : achievements & plans

Global PhPID available for all stakeholders

First pilots with FDA, WHO_UMC, UNICOM for global PhPID generation

Formation of GIDWG Phase 1: FDA/EMA/WHO-UMC

WHO-UMC endorsed as future maintenance organization for Global PhPID

2019
2021
2021
ONGOING
Proposed process for expression of Dose form

- **PhPID**: ISO 11616
- **Substance ID**: ISO 11238
- **Strength**: ISO 11240
- **Dose form**: ISO 11239

Assign dose form characteristics according to EDQM

Suspension for Injection

<table>
<thead>
<tr>
<th>0085</th>
<th>0011</th>
<th>0033</th>
<th>0047</th>
</tr>
</thead>
</table>

- **Basic Dose Form code**
- **Adm method code**
- **Intended site code**
- **Release characteristics code**
PhPID generation for Humalog Mix50 KwikPen
50 mg/ml of Insulin lispro/Insulin lispro protamine suspension, solution for injection

Substance ID: GSID-2ZT4AY1CH-1
GSID-35V9XJV9Z-5

Strength: 50.00 37 1.00 20

Dose form: 0085 0011 0033 0047

Input string: 2ZT4AY1CH1;;;;;50.00;37;1;20;;;;;;;;;;|35V9XJV9Z5;;;;;50.00;37;1;20;;;;;;;;;;|0085;0011;0033;0047

MD5 digestion: 0x073AF2E5B92AE19E8B67635AFFB3D6CA
Basis of Support for the crucial role of EDQM in IDMP

► Endorsement by the International Council of Harmonisation (ICH) of the Use of EDQM terminologies for Dose Forms and Routes of Administration for Individual Case Safety Reports in E2B(R3) message

► Endorsement of EDQM by EMA for SPOR

► Endorsement of EDQM by FDA, EMA, and WHO_UMC, the Global IDMP Implementation Working Group (GIDWG)

However, still discussion on how EDQM will be used for dose form identification.

Granular EDQM dose form versus Combination of 4 basic characteristics
Dilemma for dose form identification in IDMP

► PHPID calculation based on:

- 4 characteristics of EDQM Dose Form
  or on

- the granular EDQM dose form

Granularity

179 unique combinations of 4 basic characteristics
428 granular EDQM

With inherent information on characteristics
UNICOM Analysis of EDQM Dose Form Terminology (Standard Terms Database)
Limitations of this presentation on EDQM Dose Form

For this presentation we will focus on simple dose forms

▶ Not on:

- **Combination pack**: "Single term to describe two or more medicinal products that are packaged together and marketed under a single licence, and which are intended to be administered independently, as separate pharmaceutical products." - example: Cream + pessary

- **Combined term**: "Single term to describe a pharmaceutical dose form (or combined pharmaceutical dose form) and an item of packaging, either for the purpose of distinguishing between marketed products that differ only in the container or administration device, or where the item of packaging has special characteristics that are relevant to the use of the medicinal product." - example: Solution for injection in pre-filled syringe

- **Combined pharmaceutical dose form**: "Single term to describe two or more manufactured items that are intended to be combined in a specific way to produce a single pharmaceutical product, and which includes information on the manufactured dose form of each manufactured item and the administrable dose form of the pharmaceutical product." - example: Powder and solvent for solution for injection
UNICOM analysis of EDQM as fit for purpose to become a global terminology

► The analysis was initiated within WP8 and WP1

► Then EDQM was the subject of UNICOM webinars in the Community of Expertise

► Many items were discussed in the revision of
  the 2 ISO/CEN standards on Dose Form

► Two scientific publications
The analysis of EDQM Dose Form Terminology

- Objective
- Methodology
- Results
  - Suggestions for improvements
  - An ontology of dose forms
Objectives of the analysis

- Identify issues and propose small changes for EDQM and for the ISO/CEN revision
- Explore different combinations of characteristics of dose forms
  - to test whether such combinations are definitional
  - to create a simple ontology of dose forms
- Explore the use of such ontology of dose form in
  - the linkage of PhPID to international classifications
  - the global generation of Pharmaceutical Product Identifier PhPID
  - in the alignment of other dose form terminologies
    - (Snomed-CT, RxNorm, CDISC, WHO Drug)
Creation of a basic file for the analysis

- Obtain the freely available data from the EDQM Standard Terms (ST) API on 2021-03-17 09:52:21

- Focus on the Human (and veterinary) PDFs that are “current”

- Focus on the simple dose forms
Suggestions for improvements

- Combined values in the value sets of the characteristics
- Multiplicity: Combinations of values for a characteristic in one product
- Systemic versus local
- PDF to ADF

Resulting in a new extended spreadsheet of granular dose forms
Combined values in the existing value sets

- Combined values to be kept
  - E.g. Injection/infusion

  There is a code for injection, one for infusion, one for injection/infusion, and these different values can be implemented product by product.

- Combined values that might be split
  - E.g. Cutaneous/transdermal

  There is no code for cutaneous and no code for transdermal, while for (almost) all products it is relatively easy to determine which of the two codes would be most appropriate.
Multiplicity: Combinations of values for a characteristic in one product

For some Pharmaceutical products there can be more than one value for the characteristics of Transformation, Intended Site, or Administration Method

e.g. 50015450 cutaneous solution/concentrate for oromucosal solution
TRA dilution/no transformation

There is a code for each value, but no code for the unique combination of the values

TRA 38 dilution
TRA 42 no transformation

We introduced a temporary code for the combination, but it is not official
TRA 99905040 dilution/no transformation
Systemic versus local

► For almost all Pharmaceutical Dose Forms it is possible to determine whether the dose form is intended for systemic use or for local use

► For some dermal, buccal, rectal, nasal, inhalation dose forms this is not inherently obvious. However, when a concrete, single product is characterised, it becomes obvious

 Proposal to add a characteristic “systemic”

• Yes/No/systemic and local
• Would greatly facilitate the calculation of quality indicators for polypharmacy
  • (the use of 5 or more drugs with systemic action).
Analysis of Pharmaceutical Dose form and Administrable Dose Form

428 PDF

No transformation

Transformation(s)

285 PDF = ADF

143 PDF

2 → 4 Transformations

1 Transformation

22 PDF

121 PDF

12 a combination with « no transformation »

7 clear ADF

114 ADF

15 ambiguous

7 not identifiable
• Initial results confirm the need to make explicit the link between PDF and ADF

• Some resulting ADF are not found, or are ambiguous for some transformations

A closer look at:

- 15 ambiguous
- 7 not identifiable
<table>
<thead>
<tr>
<th>pdf_code</th>
<th>english_pdf_and_md</th>
<th>pdf_term</th>
<th>bf</th>
<th>bf_term</th>
<th>so</th>
<th>som</th>
<th>som_definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>10118000</td>
<td>powder for syrup</td>
<td>syrup</td>
<td>66</td>
<td>powder</td>
<td>97</td>
<td>solid</td>
<td>solid preparation consisting of excipients to facilitate dissolution and to be dissolved in water to obtain a</td>
</tr>
<tr>
<td>10119000</td>
<td>granules for syrup</td>
<td>syrup</td>
<td>53</td>
<td>granules</td>
<td>97</td>
<td>solid</td>
<td>solid preparation consisting of excipients to facilitate dissolution and to obtain the</td>
</tr>
<tr>
<td>10120000</td>
<td>soluble tablet</td>
<td>oral liquid</td>
<td>JARVIS Christopher: solid</td>
<td>oral suspension</td>
<td>solid</td>
<td>solid single-dose preparation consisting of a specified liquid before being swallowed.</td>
<td></td>
</tr>
<tr>
<td>10121000</td>
<td>dispersible tablet</td>
<td>oral liquid</td>
<td>JARVIS Christopher: solid</td>
<td>oral suspension</td>
<td>solid</td>
<td>solid single-dose preparation consisting of each tablet usually consisting of</td>
<td></td>
</tr>
<tr>
<td>10121500</td>
<td>dispersible tablets for doses</td>
<td>oral liquid</td>
<td>JARVIS Christopher: solid</td>
<td>oral suspension</td>
<td>solid</td>
<td>solid single-dose preparation consisting of each tablet usually consisting of</td>
<td></td>
</tr>
<tr>
<td>10122000</td>
<td>herbal tea</td>
<td>oral liquid</td>
<td>JARVIS Christopher: solid</td>
<td>oral solution</td>
<td>solid</td>
<td>solid preparation consisting of an aqueous preparation by means of a bulk form or in bags. the tea is</td>
<td></td>
</tr>
<tr>
<td>10201000</td>
<td>oral powder</td>
<td>oral solution/oral powder</td>
<td>JARVIS Christopher: solid</td>
<td>oral powder</td>
<td>solid</td>
<td>solid single-dose or multidose preparation consisting of fine powder. oral powders are intended for</td>
<td></td>
</tr>
<tr>
<td>10202000</td>
<td>instant herbal tea</td>
<td>oral liquid</td>
<td>JARVIS Christopher: solid</td>
<td>oral solution</td>
<td>solid</td>
<td>solid preparation consisting of an aqueous or another suitable liquid, but use. instant herbal teas are</td>
<td></td>
</tr>
<tr>
<td>10203000 Bu</td>
<td>oral liquid</td>
<td>oral liquid</td>
<td>JARVIS Christopher: solid</td>
<td>oral solution/oral suspension</td>
<td>solid</td>
<td>solid single-dose or multidose preparation consisting of substances and carbonates or carbon dioxide. effervescent preparations are</td>
<td></td>
</tr>
</tbody>
</table>

https://www.mdpi.com/2076-3417/12/9/4337#supplementary
From PDF to ADF with Transformation

<table>
<thead>
<tr>
<th>PDF term</th>
<th>concentrate for oral suspension</th>
</tr>
</thead>
<tbody>
<tr>
<td>PDF code</td>
<td>10100500</td>
</tr>
<tr>
<td>BDF term</td>
<td>concentrate</td>
</tr>
<tr>
<td>BDF code</td>
<td>78</td>
</tr>
<tr>
<td>SOM term</td>
<td>liquid</td>
</tr>
<tr>
<td>SOM code</td>
<td>99</td>
</tr>
<tr>
<td>ADF term</td>
<td>oral suspension</td>
</tr>
<tr>
<td>ADF code</td>
<td>10106000</td>
</tr>
<tr>
<td>ADF BDF term</td>
<td>suspension</td>
</tr>
<tr>
<td>ADF BDF code</td>
<td>85</td>
</tr>
<tr>
<td>ADF SOM term</td>
<td>liquid</td>
</tr>
<tr>
<td>ADF SOM code</td>
<td>99</td>
</tr>
</tbody>
</table>
Further develop the file

- Implemented proposed changes:
  - Split of cutaneous/transdermal
    - ISIC_SPLIT
  - Introduction of new values in the value set for TRA, ISI, AME for unique combinations of multiple values
    - TRAC
    - AMEC
  - Systemic / Non Systemic

A new, more complex spreadsheet with 428 extended rows: to be verified
Development of an Ontology of Dose Form
Analysis of Unique combinations of characteristics

List of items to be considered in the combination process:

- BDF: Basic Dose Form of Pharmaceutical Dose Form
- SOM: State of Matter of Pharmaceutical Dose Form
- ADF_BDF: Basic Dose Form of Administrable Dose Form
- ADF_SOM: State of Matter of Administrable Dose Form
- TRAC: Transformation Combined
- RCA: Release Characteristics
- ISI_SPLIT: Intended site (with cutaneous and transdermal apart)
- AMEC: Administration Method Combined
- SYS: Systemic of local
Analysis of unique combinations in different sets of descriptors and characteristics of EDQM dose forms.

(a) Analysis Not Taking “Systemic/Local” into Account

<table>
<thead>
<tr>
<th>Analysis</th>
<th>Descriptors</th>
<th>Characteristics</th>
<th>Total Number of Unique Combinations (UC)</th>
<th>Unique Combinations (UC) with 1 Occurrence</th>
<th>Unique Combinations (UC) with 2+ Occurrences</th>
<th>Sum of Occurrences in Unique Combinations 2+</th>
<th>Sum of Occurrences in UC2+ and in UC1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analysis 1</td>
<td>x</td>
<td>x</td>
<td>377</td>
<td>340</td>
<td>37</td>
<td>88</td>
<td>428</td>
</tr>
<tr>
<td>Analysis 2</td>
<td>x</td>
<td>x</td>
<td>349</td>
<td>295</td>
<td>56</td>
<td>135</td>
<td>428</td>
</tr>
<tr>
<td>Analysis 3</td>
<td>x</td>
<td>x</td>
<td>192</td>
<td>113</td>
<td>79</td>
<td>315</td>
<td>428</td>
</tr>
<tr>
<td>Analysis 4</td>
<td>x</td>
<td>x</td>
<td>195</td>
<td>78</td>
<td>117</td>
<td>350</td>
<td>428</td>
</tr>
</tbody>
</table>

(b) Same Analysis but Now Taking “Systemic/Local” into Account

<table>
<thead>
<tr>
<th>Analysis</th>
<th>Descriptors</th>
<th>Characteristics</th>
<th>Total Number of Unique Combinations (UC)</th>
<th>Unique Combinations (UC) with 1 Occurrence</th>
<th>Unique Combinations (UC) with 2+ Occurrences</th>
<th>Sum of Occurrences in Unique Combinations 2+</th>
<th>Sum of Occurrences in UC2+ and in UC1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analysis 1</td>
<td>x</td>
<td>x</td>
<td>383</td>
<td>350</td>
<td>33</td>
<td>78</td>
<td>428</td>
</tr>
<tr>
<td>Analysis 2</td>
<td>x</td>
<td>x</td>
<td>357</td>
<td>306</td>
<td>51</td>
<td>122</td>
<td>428</td>
</tr>
<tr>
<td>Analysis 3</td>
<td>x</td>
<td>x</td>
<td>206</td>
<td>128</td>
<td>78</td>
<td>300</td>
<td>428</td>
</tr>
<tr>
<td>Analysis 4</td>
<td>x</td>
<td>x</td>
<td>274</td>
<td>197</td>
<td>77</td>
<td>231</td>
<td>428</td>
</tr>
</tbody>
</table>

Descriptors: Basic Dose Form (BDF) and State of Matter (SOM) of Pharmaceutical Dose Form (PDF) and Administrable Dose Form (ADF)

Characteristics:
- Transformation (TRAC): 6 values; dilution, dissolution, dispersion, mixing, no transformation, unknown.
- Release Characteristics (RC): 4 values; conventional, prolonged, delayed, modified.
- Intended Site Split (ISI-s): 25 values; example: cutaneous; oral (see Supplementary file for full list).
- Administration Method (AMEC): 19 values; example: application; inhalation; injection. (see supplementary file for full list).
- Systemic/Local: 4 values; systemic, local, local/systemic, unknown.

Analysis 1: Taking all descriptors and all characteristics into account
Analysis 2: Taking the descriptors of the administrable dose form and all characteristics into account
Analysis 3: Taking only all characteristics into account
Analysis 4: Taking the Basic Dose Form of the Administrable Dose Form, RC, ISI-s, and AMEC into account (analogy the FDA/WHO_SIMC pilot approach)

Unique combinations (UC) with 1 occurrence: a specific combination of the values of descriptors and/or characteristics, represented by one PDF

Can be considered as a measure of granularity of the dose form terminology and an indicator of congruence with the textual definition

Unique combinations with 2 or more occurrences (UC2+): a specific combination of the values, represented by two or more PDFs

Can be considered as a measure of aggregation for onologic class creation

Sum of occurrences in UC2+; the number of PDFs grouped in unique combinations of values with 2 or more occurrences of dose forms

Can be considered as an additional measure of granularity for onologic class creation

Total number of unique combinations: sum of UC and UC2+

Can be considered as an additional measure of granularity of the dose form terminology

Check: the sum of UC and the sum of the occurrences in UC2+ must always be 428 (grey cells)
Conclusion of the analysis of unique combinations

- Full use of all characteristics makes the unique combinations almost definitional

- Looking at different unique combinations helps to group similar PDFs

- This exercise is useful to create a small ontology of Dose Forms
Methodology to create the ontology of dose forms

Starting point
We used the revised excel file with extended characteristics and PDF/ADF alignment
We looked at the most aggregated unique combinations of characteristics

Ordering exercise
We ordered them by Intented Site
Within each group we listed first the PDFs with no transformation (hence ADFs)

Grouping exercise
We splitted groups of PDFs when there was a clinical reason to do so
We concatenated groups of PDFs when there was no clinical reason to keep them separated.

Naming exercise
We named the resulting groups
Building of a simple Dose Form ontology in 3 levels

Level 1: Granular Level of Aggregation:

428 EDQM PDFs

Level 2: Intermediate Level of Aggregation

65 Dose form Groups

Level 3: High level of aggregation

25 Intented Sites
This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 875299

### Resulting Ontology of Dose Form

- **Proposal for small ontology of dose form terminology**

<table>
<thead>
<tr>
<th>AURICULAR</th>
<th>ORAL, CONVENTIONAL-RELEASE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Auricular dose form</td>
<td>Oral solid dose form</td>
</tr>
<tr>
<td>Auricular/nastril dose form</td>
<td>Oral semi-solid dose form</td>
</tr>
<tr>
<td>Auricular/nastril/ocular dose form</td>
<td>Oral drops dose form</td>
</tr>
<tr>
<td>Auricular/ocular dose form</td>
<td>Oral liquid dose form</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CUTANEOUS</th>
<th>ORAL, MODIFIED-RELEASE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cutaneous dose form</td>
<td>Oral effervescent or dispensible dose form</td>
</tr>
<tr>
<td>Cutaneous/transdermal dose form</td>
<td>Oral/rectal dose form</td>
</tr>
<tr>
<td>Cutaneous/nastril dose form</td>
<td>Oral gastro-resistant dose form</td>
</tr>
<tr>
<td>Cutaneous/oral/rectal dose form</td>
<td>Oral prolonged-release dose form</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DENTAL</th>
<th>OTHER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dental dose form</td>
<td>Orale oral modified-release dose form</td>
</tr>
<tr>
<td>ENDOCERVICAL</td>
<td></td>
</tr>
<tr>
<td>Endocervical dose form</td>
<td></td>
</tr>
<tr>
<td>EXTRA/ORTHOPEDAL</td>
<td></td>
</tr>
<tr>
<td>Extracorporeal dose form</td>
<td></td>
</tr>
</tbody>
</table>

| EXTRACORPOREAL/PARENTERAL |                                             |
| Dialysis dose form |                                             |
| GASTRIC              |                                             |
| Gastric dose form    |                                             |
| GASTROENTERAL        |                                             |
| Gastrontral dose form |                                             |

| INTRAPERITONEAL      |                                             |
| Intraperitoneal dose form |                                             |
| INTRAVENOUS          |                                             |
| Intravenous dose form |                                             |
| Intravenous device   |                                             |
| INTRAVESICAL         |                                             |
| Intravesical/intraluminal dose form |                                             |

| OCULAR               |                                             |
| Ocular semi-solid dose form |                                             |
| Ocular drops dose form    |                                             |
| Ocular insuff dose form   |                                             |
| Ocular intravascular dose form |                                             |
| Ocular prolonged-release dose form |                                             |

| NASAL                |                                             |
| Nasal spray dose form |                                             |
| Nasal solid or semi-solid dose form |                                             |
| Nasal drops dose form |                                             |

| ENDOMETRICAL         |                                             |
| Endometrial dose form |                                             |

| NASAL/OCULAR/PULMONARY |                                             |
| Endometrial/pulmonary dose form |                                             |

| MISCELLANEOUS        |                                             |
| Radiopharmaceutical dose form |                                             |
| Wound dressings prolonged-release dose form |                                             |

| Uncategorised        |                                             |
| Dose form            |                                             |
Visualising the ontology with WebProtégé
65 intermediary level dose form groupers
Connecting RxNorm to the ontology

- RxNorm has been connected to the small ontology by Natalie Karapetian (Harvard)
- Given the similarity between SNOMED-CT and EDQM, connecting SNOMED-CT should be easier

EDQM standard terms database

RxNorm dose forms
Multilinguality and EDQM

For the 428 PDF labels,
  Lexical equivalents are available for 34 Languages
    The official EU languages
      Albanian, Bosnian, …, Turkish and Ukrainian

For the value sets of the characteristics in English
  lexical equivalents are not available yet
    BDF, SOM
    TRA, RCE, ISI, AME
A real world example:
Will this be useful for cross-border exchange of prescriptions, medication lists and patient summaries?
What if a Greek patient shows up on in a Belgian Pharmacy and requests a prescription for αμλοδιπίνη

By identifying the IDMP data on the box, the pharmacist realizes that this about

amlodipine,
and more specifically
amlodipine oral 10 mg,
and even more specifically:
amlodipine besilate capsule, hard 10mg

In Belgium available as: Amlor 10 mg (Upjohn), and in generics by a number of companies but as tablets
# Real world example

## Example of aggregated representation of medicinal products at work

**Grouper of Medicinal Products with the same active moiety of substance**

- C08CA01 amlodipine

### Virtual Medicinal Product Group

- amlodipine oral 10 mg
- amlodipine oral 5 mg

### Pharmaceutical Product

<table>
<thead>
<tr>
<th>Product</th>
<th>Dosage</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>amlodipine besilate capsule, hard</td>
<td>10 mg</td>
<td></td>
</tr>
<tr>
<td>amlodipine besilate tablet</td>
<td>10 mg</td>
<td></td>
</tr>
</tbody>
</table>

*(note: amlodipine maleate film-coated tablet 10 mg recently disappeared from the Belgian market)*

<table>
<thead>
<tr>
<th>Product</th>
<th>Dosage</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>amlodipine besilate capsule, hard</td>
<td>5 mg</td>
<td></td>
</tr>
<tr>
<td>amlodipine besilate tablet</td>
<td>5 mg</td>
<td></td>
</tr>
</tbody>
</table>

### Medicinal Product (Belgium)

<table>
<thead>
<tr>
<th>Product</th>
<th>Dosage</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>amlodipine besilate capsule, hard</td>
<td>10 mg</td>
<td></td>
</tr>
</tbody>
</table>

- Amlor harde caps. 10 mg Upjohn

<table>
<thead>
<tr>
<th>Product</th>
<th>Dosage</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>amlodipine besilate tablet</td>
<td>10 mg</td>
<td></td>
</tr>
</tbody>
</table>

- Amlodipine EG (PIP) tabl. (deelb.) Besilate 10 mg PI-Pharma
- Amlodipine EG tabl. (deelb.) Besilate 10 mg EG
- Amlodipine Mylan tabl. (deelb.) Besilate 10 mg Mylan
- Amlodipine Teva tabl. (deelb.) 10 mg Teva
- Amlodipin Sandoz (Impexco) tabl. (deelb.) Besilaat 10 mg Impexco
- Amlodipin Sandoz tabl. (deelb.) Besilaat 10 mg Sandoz
- Amlodemed tabl. (deelb.) 10 mg 3DDD
- Amlodipin AB tabl. 10 mg Aurobindo
- Amlodipin Sandoz tabl. (deelb.) Besilaat 10 mg Sandoz

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A question to EDQM Management:
What is the position on the right way to use EDQM in identifying dose form?
Dilemma for dose form identification in IDMP

- PHPID calculation based on:
  - 4 characteristics of EDQM Dose Form
  - Or on
  - The granular EDQM dose form

**Granularity**

- 179 unique combinations of 4 basic characteristics
- 428 granular EDQM

With inherent information on characteristics
Recapitulation of our questions to the EDQM Standard Terms Working Party
Recapitulation of our questions

1. Could you verify our extended Excel File of 428 PDFs?
   ▶ Provide codes for combinations of values for characteristics
   ▶ Opinion on splitting “cutaneous/transdermal”
   ▶ Check of alignment of PDF to ADF
   ▶ Opinion on a new characteristic “systemic”

2. Would you cooperate in making the ontology of dose form better?
   ▶ Participation in Alignment of RxNorm to the EDQM ontology
   ▶ Participation in experiments on Substitution rules in cross border prescription exchange
   ▶ Participation in experiments to find the best way to train legacy conversion experts in standardization of dose form to EDQM

3. Do you feel the need to reflect on the best way to represent Dose Form in IDMP implementation and PhPID creation?
Thank you for your attention. Time for questions?
References


## Virtual Drug Models

In

**IDMPM**

**Snomed-Ct**

**RxNorm**

**Dm+D/SAM**

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### Medicinal Products

### "Exact" abstract representation

### Higher level aggregation
Cherry blossoms are cherry blossoms and not hedge bindweeds
They are pink, delicate and blossom in the spring
Yet, every cherry blossom is unique