Find your way in Standard terms; PharmEuropa; Knowledge database & Ph. Eur. online

2019 Training Session
“The European Pharmacopoeia”
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EDQM Head of Reference Standards & Logistics Department
10 – 11 September 2019, Iselin, New Jersey, USA
TOPICS

- How to access?
- Standard Terms
- Knowledge database
- Pharmeuropa online

How to access?
### HOW TO ACCESS?

Specific page to EDQM databases from the EDQM website:  

#### Databases

<table>
<thead>
<tr>
<th>Pharmepro</th>
<th>Pharmacopoeia Risk &amp; Scientific News</th>
<th>Pharmepro Publications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmepro provides public reports on drug European trends on a number of general and specific official and non-official European and national standards.</td>
<td>Pharmepro Risk &amp; Scientific News contains all the news in the biological domain: recent and international standards linked to the European Pharmacopoeia.</td>
<td>Publish the latest publications available for free (PDF).</td>
</tr>
<tr>
<td>Knowledge</td>
<td></td>
<td>Access the EDQM publications available for free (PDF).</td>
</tr>
<tr>
<td>Knowledge is a searchable database of information on a given substance or general method of analysis and also contains information such as the harmonisation process leading the pharmacopoeia in PDF format. The links to the reference standard profiles, the trade names of some medicines, such as pharmaceuticals, homeopathic and biological, and the specific country regulations are also included.</td>
<td>Merck</td>
<td>Access the PDFs.</td>
</tr>
<tr>
<td>Merck</td>
<td>Merck</td>
<td>Access the PDFs.</td>
</tr>
</tbody>
</table>

#### EDQM Standard Terms

**WTO Q&A**
- WTO database contains information on WTO (International Uniform Reference Substance, IURS).
- Search WTO (IURS) standards.
- More about WTO (IURS) standards.
- Place an order.

**WTO CRS**
- WTO database contains information on WTO (International Uniform Reference Substance, IURS).
- Search WTO (IURS) standards.
- More about WTO (IURS) standards.
- Place an order.

#### Certification

- Search our Certification Database for information on Certificates of Suitability (CDS) granted by the EDQM.
- Search Certification Database.
- Certification fees.

#### Standards

- The standard terms database contains terms and definitions to describe pharmaceutical drug terms, and is a useful tool for pharmacists, clinicians, medical professionals, students, and pharmaceutical companies.
- Search Standard Terms Database.

#### Medicines

- Database on the legal classification of medicines as regards their supply conditions and details of prescription status.
- Search Medicines.
Standard Terms – a brief history

• The lists of Standard Terms were initially drawn up by the European Pharmacopoeia Commission further to a request from the EU Commission

• It was recognised that a harmonised set of terms was needed across Europe to describe medicinal products

• Standard Terms are intended for use in the marketing authorisation application (MAA), summary of product characteristics (SmPC), labeling, and electronic communications…. and more

Standard Terms – a brief history

• Standard Terms was originally a printed publication, first appearing as a special issue of Pharmeuropa in October 1996

• Updated versions were published every couple of years until December 2004 and replaced by an online database version in 2005

• An entirely new version of the database was released in November 2014 with major updates released in March 2016 and August 2017

• Change requests can now be accepted for assessment by the Standard Terms Working Party from authorities outside of the Ph. Eur. member states who wish to use Standard Terms themselves, in particular the ICH regions
Standard Terms – overview

- Standard Terms are controlled vocabularies that are used to describe certain attributes of a medicinal product (human and veterinary) from a regulatory perspective:
  - Pharmaceutical dose forms (i.e. dosage forms)
  - Routes or methods of administration
  - Certain important packaging items such as Containers, Closures and Administration devices
  - Combined pharmaceutical dose forms, Combined terms, Combination packs
  - Patient-friendly terms
  - Units of presentation

Standard Terms – International relevance

- EDQM Standard Terms is recognised within Europe and in other regions as the preferred terminology source for dose forms, routes of administration etc. for regulatory uses, for IDMP and for adverse event reporting (pharmacovigilance reporting)

- The scope of Standard Terms has been widened to meet the requirements of IDMP and ICSRs for pharmacovigilance, not just for marketing authorisation applications and labelling

- IDMP: Identification of Medicinal Products

- Project originally developed in ICH and eventually resulted in a set of 5 International Standards developed in ISO TC 215 WG 6

- Developed to meet a demand for internationally harmonised specifications for the unique identification of medicinal products
Standard Terms – International relevance

- When all of the IDMP standards are implemented, they will support the implementation of the Individual Case Safety Report (ICSR) standards (ISO/HL7 27953)

- ICSR standards provide a harmonised framework for adverse event reporting, and require harmonised controlled vocabularies in order that different regions can communicate effectively with each other

  The overall purpose is to improve pharmacovigilance on a global scale

Standard Terms – additional features

- Application Programming Interfaces (APIs, or web services) allow external systems to interact directly with the database and extract data for use in their own systems on a regular basis, in order to ensure that they remain up to date

- A mapping feature allows owners of similar lists of controlled vocabularies to add their own terms in a separate section and map them to the equivalent Standard Term(s)

- Tagging allows the inclusion of ‘non-traditional’ terms that are intended not for use in marketing authorisation applications and labelling, but exclusively for other purposes, such as adverse-event reporting (e.g. terms such as ‘Transplacental’)

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Standard Terms working procedure

• Change requests for Standard Terms can be submitted to the EDQM by national authorities only or directly to the EDQM (outside Europe)

• The Standard Terms Working Party consults on the request and, if appropriate, creates or revises a Standard Term

• A definition is included and, for some classes of terms, additional characterising information is provided

• After adoption, new or revised terms are added to the Standard Terms database in English

• Translations can then be submitted by national authorities and, after validation, appear in the Standard Terms database

Standard Terms languages

• Standard Terms are currently available in 34 languages, including several from non-EU regions:

  • Albanian, Bosnian, Bulgarian, Chinese, Croatian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Icelandic, Italian, Kazakh, Latvian, Lithuanian, Macedonian, Maltese, Norwegian, Polish, Portuguese, Romanian, Russian, Serbian, Slovakian, Slovenian, Spanish, Swedish, Turkish, Ukrainian (plus Japanese for mapped ICH terms only)
Standard Terms access

- Access to Standard Terms is available free of charge
- Full instructions on how to register and create an account are available on the website

https://standardterms.edqm.eu

Example of a Standard Term

Powder for solution for injection
### Status

**Term in English:** Powder for solution for injection

**Domain:** Human and Veterinary

### Specific Information Tabs

- **Details**
- **Characteristics**
- **Translations**
- **Linked Terms**
- **Summary Sheets**

### Most Important Information Appears under 'Details'

- **Concept Code:** 1125000
- **Term:** Powder for solution for injection
- **Definition:** Solid sterile preparation consisting of one or more powders, including freeze-dried powders, intended to be dissolved in the specified liquid to obtain a solution for injection.
- **Ph. Eur. Monograph:** 0520
- **Domain:** Human and Veterinary
- **Concept Status:** Current
- **Version Number:** 2
- **Version Creation Date:** 2016-03-30 18:50:20
- **Language:** English
- **Expanded Code:** PEP-1125000-EN-00
- **Concept Creation Date:** 2005-03-14 00:00:00

### This Tab is Specific to Pharmaceutical Dose Forms

- **State of matter:** Solid
- **Basic dose form:** Powder
- **Administration method:** Injection
- **Intended site:** Parenteral
- **Release characteristics:** Conventional
- **Transformation:** Solution

### This Information is Used to Sort and Arrange Pharmaceutical Dose Forms
## Translations

<table>
<thead>
<tr>
<th>Language</th>
<th>Term in Language</th>
<th>Version Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>English</td>
<td>Powder for solution for injection</td>
<td>2016-03-30</td>
</tr>
<tr>
<td>French</td>
<td>Poudre pour solution injectable</td>
<td>2006-09-14</td>
</tr>
<tr>
<td>Italian</td>
<td>Polvere per soluzione iniettabile</td>
<td>2006-03-14</td>
</tr>
<tr>
<td>Spanish</td>
<td>Polvo para solución inyectable</td>
<td>2006-03-14</td>
</tr>
<tr>
<td>Portuguese</td>
<td>Pó para solução injetável</td>
<td>2014-03-10</td>
</tr>
<tr>
<td>Romanian</td>
<td>Pulbere pentru soluție injecțibilă</td>
<td>2006-03-14</td>
</tr>
<tr>
<td>German</td>
<td>Pulver zur Herstellung einer Injektionslösung</td>
<td>2006-03-14</td>
</tr>
<tr>
<td>Dutch</td>
<td>Poeder voor oplossing voor injectie</td>
<td>2006-03-14</td>
</tr>
<tr>
<td>Greek</td>
<td>Σκόνη για υπόδειγμα</td>
<td>2006-03-14</td>
</tr>
<tr>
<td>Hebrew</td>
<td>גברון לה svenska</td>
<td>2006-03-14</td>
</tr>
<tr>
<td>Danish</td>
<td>Støv for injektionsløsning</td>
<td>2006-03-14</td>
</tr>
<tr>
<td>Polish</td>
<td>Pó do preparado do preparado</td>
<td>2006-03-14</td>
</tr>
</tbody>
</table>

## Versioning Information

Terms are currently available in 34 languages (plus Japanese for mapped ICH terms only).

National authorities create and submit translations to the EDQM.
### Combined pharmaceutical dose form
- Powder and solution for injection
- Powder and solvent for solution for injection
- Powder and solvent for solution for injection/infusion
- Powder and solvent for solution for injection/skin-prick test

### Combined term
- Powder and solvent for solution for injection in cartridge
- Powder and solvent for solution for injection in pre-filled pen
- Powder and solvent for solution for injection in pre-filled syringe

### Patient-friendly term
- Powder for injection

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**Hyperlinks to related Standard Terms**

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**Summary sheets that can be downloaded in PDF format**
Example of a mapped term

Intrathecal use

This tab appears when there are mapped terms
Each external organisation/database has its mapped terms listed together.

Clicking on one of the mapped terms will take you to the entry for that particular mapped term.

The ICH E2B Code List has terms in English and Japanese that are equivalent to the Standard Term ‘Intrathecal use’.

Regional information for the term can be indicated here, including a definition, comments, and links to the external database, where available.
Example of a ‘non-traditional’ Standard Term

Transplacental

The ST tag has been replaced with the AER tag, to indicate that it is not a traditional Standard Term but is instead intended for use in adverse-event reports.

This term is not intended to be used to describe an authorised route of administration. However, an official, harmonised term is necessary for AERs in order to describe exposure to a drug in utero, hence its inclusion as a Standard Term.
Pharmeuropa online

PHARMEUROPA ONLINE

• Free of charge (but requires registration).
• Contains texts under public enquiry (Pharmeuropa); Bio & Scientific notes; some technical information and archives.
Pharmeuropa (Texts for comments)

- The forum of the Ph. Eur.
- Continuous publication.
- 4 “issues” (with corresponding deadlines) per year.

Notes:

* Corrections are not included in Pharmeuropa.

* Comments from the USA: through EDQM Helpdesk.

* You can subscribe to notifications!
  My Account > Configure Notifications >
Pharmeuropa Bio & Scientific Notes
Provides access to establishment reports of BRPs
Search engine available.

Pharmeuropa archives
Provides access to Pharmeuropa dated back 1987
Search engine available.
Other types of information are also available such as:

- New texts for comment,
- List of texts adopted at the EP Commission
- Publication schedule
- Comments about texts revised in the 10th edition

What’s new?

Other types of information are also available such as:

- Draft harmonised texts for comment
- PDG state of work

Pharmacopoeial harmonisation
Other types of information are also available such as:

- You have the possibility to express opinion in response to an article in Pharmeuropa Bio & Scientific Notes

Reader’s tribune

Other types of information are also available such as:

- Policies, explanation to Ph. Eur. monographs
  - e.g. clarification of legal status: Ph. Eur. Section 3. Materials for containers and containers; response and correction factors in monographs; reverse osmosis in Ph. Eur. monograph Water for injections (0169), etc.

Technical information
Other types of information are also available such as:

- 10th edition
- Work of the Ph. Eur., procedures
- Procedure to comment, addresses of NA, etc.

Useful information

Other types of information are also available such as:

- Provides access to other EDQM publications such as:
  - Standard terms,
  - European Paediatric Formulary,
  - Blood, organ, tissue and cell transplantation guides,
  - Proceedings of International Conferences,
  - Ph. Eur. technical guides...
Knowledge database

KNOWLEDGE DATABASE

• How to connect?

Direct link from electronic Ph. Eur.

2D code in print edition
On-going revision
- Aim of the revision
- State of work
- The number of the last issue of Pharmeuropa in which a draft of the monograph was published

RS used in the monograph

Chromatogram

Type chromatogram is available for download.

It should be stressed that such chromatograms do not constitute a mandatory part of the corresponding monograph and are provided for information only. They do not necessarily include all impurities mentioned in the monograph, are not representative for all impurity profiles of the substance and are provided solely for the convenience of the user.
SUPPLEMENT 9.4
Identification: 1st Identification series updated and only IR now required; IR sample preparation deleted in accordance with current policy; 2nd Identification series updated to avoid using potassium dichromate (test D) and only a mixed melting point now described.

Related substances: new LC to take into account additional impurities.

EDITION 9.0
Heavy metals: test deleted in line with Ph. Eur. strategy on elemental impurities.

EDITION 6.0: corrected

History

Contains information concerning certain technical modifications to some revised/corrected texts published since Ph. Eur. 5.0.
This information complements the modifications indicated by lines in the margin in the supplements and is not necessarily exhaustive.

KNOWLEDGE DATABASE

For guidance purposes: provides additional information to users e.g. column / trade names
Updated at each revision!

If certificate(s) of suitability have been granted for the substance in question, the list of certificates is shown.
This is an excerpt from the online List of CEP.

<table>
<thead>
<tr>
<th>Certificate Number</th>
<th>Certificate Holder</th>
<th>Issue Date</th>
<th>Status</th>
<th>End Date</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>CEP</td>
<td>New Zealand Nuclear Laboratories Ltd</td>
<td>01/10/2018</td>
<td>VALID</td>
<td>01/10/2018</td>
<td>Chemistry</td>
</tr>
<tr>
<td>CEP</td>
<td>Johnson Matthey, Inc.</td>
<td>01/10/2018</td>
<td>VALID</td>
<td>01/10/2018</td>
<td>Chemistry</td>
</tr>
<tr>
<td>CEP</td>
<td>Rhodia, Inc.</td>
<td>01/10/2018</td>
<td>VALID</td>
<td>01/10/2018</td>
<td>Chemistry</td>
</tr>
<tr>
<td>CEP</td>
<td>Ciba Specialty Chemicals</td>
<td>01/10/2018</td>
<td>VALID</td>
<td>01/10/2018</td>
<td>Chemistry</td>
</tr>
<tr>
<td>CEP</td>
<td>Sigma-Aldrich</td>
<td>01/10/2018</td>
<td>VALID</td>
<td>01/10/2018</td>
<td>Chemistry</td>
</tr>
</tbody>
</table>

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Ph. Eur. online

Ph. Eur. ONLINE

• New platform for the 10th edition

• EDQM has been using same platform for Ph. Eur. since 2007.

• The website needed modernising. We decided to redevelop the site internally using Python Programming Language.

• Ph. Eur. electronic version is part of a more global project which includes the PaedForm website and Pharmeuropa
Ph. Eur. ONLINE

• New platform for the 10th edition
  • Minimum: ISOFunctional vs previous version
  • Completely cumulative versions, bilingual (English and French), with new features and direct access to complementary information (Knowledge Database).
  • Application fully compatible with recent Windows and Linux operating systems (Mac coming soon).

Other new features

• New subscription model
• Online version is tablet and smartphone friendly
• Direct links to texts
• Improved search query management
• Improved visibility of changes (for revised and corrected texts)
• Improved browsing
  • In the table of contents and between search results
  • Using standard browser buttons (back/forward arrows)
• Same username and password as for many other Ph. Eur. Websites as uses same authentication database (OCABR, OMCL, KnowX, PaedForm, future Pharmeuropa)
Ph. Eur. ONLINE

- **New management of licences**

  - No more safeview plugin. Content protection is ensured by identifying users individually and preventing simultaneous access.
  - Individual use: installation of the application to 1 computer and to 1 USB stick, for online or offline use, for easy access while on the move or in environments where the use of the book or the website would not be possible or would be impractical.
  - Shared use: installation of the application to computers or USB sticks and use whether connected to internet or not, for example for non-nominative access in university libraries or laboratories.

- **NEW possibility to use the arrows.**
- **NEW layout to access General Notices & General monographs.**
- **NEW possibility of advanced queries and saving them.**
Ph. Eur. ONLINE

- Query in 5 texts; for contains “Fluorescence” & “methylene”.
- ! In French query only with accent (é / è, etc.)
- Now possible to save queries

Ph. Eur. ONLINE

- Possibility to download the version on an USB stick

- “Download” menu, select the application, copy files on the USB stick, execute the .exe, enter id and code.
• Click on « Start-for-windows.exe » ....... and start working...

• Possibility to work online and offline.

• ! Your queries could be lost on the device, please check before.

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• Subscribers to electronic and print versions have access to Ph. Eur. archives.
  • Only subscribers with an up-to-date subscription have access
• Ph. Eur. Archives will be more dynamic than previously
• HTML versions will be moved directly to the Ph. Eur. Archives when they are no longer implemented
  • January 2020: Ph. Eur. 9.8 → Ph. Eur. Archives
  • April 2020: 10.0
  • July 2020: 10.1
  • January 2021: 10.2, etc.

• Ph. Eur. Archives will remain in PDF format
Thank you for your attention

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