Find your way in Pharmeuropa, the Knowledge database & Ph. Eur Online

European Pharmacopoeia Training Webinar
8 July 2020
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How to access publications and databases

- A specific page on the EDQM website contains links to the various EDQM publications and databases – the link can be found under ‘Useful information’ at the bottom of the www.edqm.eu website

https://www.edqm.eu/en/databases
How to access publications and databases

Ph. Eur. Online

https://pheur.edqm.eu
Ph. Eur. Online

- New platform for the 10th Edition
- Completely cumulative versions, bilingual (English and French), with new features and direct access to complementary information (Knowledge Database)
- Access to the European Pharmacopoeia Online website is possible from all recent common operating systems
- Tablet and smartphone friendly
- Downloadable application fully compatible with recent Windows and Linux operating systems (Mac version is in progress)
- Choice of two installation options for each electronic licence: either individual access or shared access (e.g. university library or laboratory)

Ph. Eur. Online

- 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 authentication database means the same username and password are used for various other EDQM websites (Pharmeuropa, PaedForm, OCABR, OMCL, KnowX)
Ph. Eur. Online

• Subscribers to electronic and print versions have access to Ph. Eur. archives.

• 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 → Ph. Eur. Archives
  • July 2020: 10.1 → Ph. Eur. Archives
  • January 2021: 10.2, etc.

• Ph. Eur. archives are provided in PDF format
Possibility to download to a USB stick

Via the 'Download' menu, select the application, copy files on the USB stick, run the EXE file, enter ID and code.
Pharmeuropa

• Pharmeuropa has recently been rebuilt using the same platform as Ph. Eur. Online
• It was released at the end of January 2020
• The layout and functionality are similar to those of the previous site
• There is now single-sign-on for Ph. Eur. Online, Pharmeuropa and PaedForm

https://pharmeuropa.edqm.eu
Pharmeuropa

• Access is free of charge

• It contains texts under public enquiry, Bio & Scientific Notes, Pharmeuropa Archives, Technical information, Useful information etc.

Pharmeuropa – Texts for comment

• The forum of the European Pharmacopoeia

• 4 ‘issues’ per year, with corresponding deadlines for comments

• Note: for new and revised texts only (corrections and minor revisions are not published in Pharmeuropa)
Pharmeuropa – Bio & Scientific Notes

- Provides articles and feedback from users of the Ph. Eur. related to pharmaceutical quality control
- Includes establishment reports for biological reference preparations (BRPs)
Pharmeuropa – Archives

- Provides access to Pharmeuropa dating back to 1987, including special issues
- Browse by year and issue or search for key words with the search engine
Pharmeuropa

What’s new?

• EDQM News and events
• Status of Pharmeuropa issues and new texts
• Comments about texts revised in the last supplement

Pharmeuropa

Pharmacopoeial harmonisation

• Draft harmonised texts for comment
• PDG state of work
Readers’ Tribune

- Discussion articles and letters commenting on policies or decisions of the Ph. Eur. Commission
- Opportunity for users to express opinions in response to articles in Pharmeuropa Bio & Scientific Notes

Technical information

- Policies and explanations related to Ph. Eur. texts, for example:
  - legal status of Section 3 on materials for containers
  - reverse osmosis in water for injections (0169)
  - response and correction factors on Ph. Eur. monographs
Pharmeuropa

Useful information

- Publication schedules, adopted texts, lists of published texts, etc.
- Work of the Ph. Eur.: procedures for elaboration of texts, procedure for commenting, NA addresses, etc.
- Links to HelpDesk, FAQs, Certification, etc.

Pharmeuropa

Publications

- Links to other EDQM publications, such as:
  - Standard Terms
  - European Paediatric Formulary (PaedForm)
  - Blood, organ, tissue and cell transplantation guidelines
  - Proceedings of international conferences
  - Ph. Eur. technical guides, etc.
Knowledge Database

- Provides additional information on a substance or general text
- The database is accessible free of charge
- Its aim is improve transparency for users, in turn making it easier to contribute to the work of the European Pharmacopoeia
- Links are provided to relevant information such as chromatograms, reference standards, trade names for certain reagents (e.g. chromatography columns and biological kits), and holders of Certificates of Suitability to the monographs of the European Pharmacopoeia (CEPs)

Knowledge Database

• The Knowledge database can be accessed directly from the Ph. Eur. Online by clicking on the link at the top of the text
• Or via the 2D barcode in the print edition using a smartphone/tablet equipped with a camera and a barcode-reader app

On-going revision

• State of work
• Last Pharmeuropa issue in which a draft was published
• Aim of the revision

State of work

0 The monograph has been authorised but work has not started yet
1 Work has started (first draft)
2 The monograph has been authorised for publication in Pharmeuropa (see Pharmeuropa number)
3 The monograph has been submitted for adoption to the European Pharmacopoeia Commission
4 The monograph has been adopted
5 The monograph is about to be published, or has been published

Paracetamol

DEFINITION
N-(4-Hydroxyphenyl)acetamide.
Content: 99.0 per cent to 101.0 per cent (dried substance).

C₇H₈NO₂
M₁₅₁.2

04/2018:0049
Chromatogram

- Indicates whether one or more chromatograms are available for download
- Such chromatograms are provided for information only and are not a mandatory part of the corresponding monograph
- They do not necessarily include all impurities mentioned in the monograph
Knowledge Database

**History**

- Non-exhaustive information concerning certain revisions and corrections since Ph. Eur. 5.0
- **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

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Knowledge Database

**Reference standards**

- Lists the reference standards that are used in the monograph, providing links to the CRS database
Knowledge Database

Practical information

• For guidance purposes, providing additional information to users, e.g. columns, trade names

• This information is updated at each revision

Certificates of suitability

• If any certificates 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 CEPs

Thank you for your attention

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LinkedIn: https://www.linkedin.com/company/edqm/
Twitter: @edqm_news
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