Find your way in Pharmeuropa, the Knowledge database & Ph. Eur. Online: Useful hints and other practicalities

European Pharmacopoeia Training Session on Biologicals
4-5 February 2020

Dr Hans-Joachim Bigalke, Head of IT and Publications Division, EDQM, Council of Europe
TOPICS

- How to access?
- Pharmeuropa Online
- Ph.Eur. Online
- Knowledge database

HOW TO ACCESS?

Specific page to EDQM databases from the EDQM website:
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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 but ...  
  ... 4 “issues” (with corresponding deadlines) per year.

**Notes:**

* Corrections, minor revisions are not included.

* **Comments** from the non Ph Eur countries e.g. USA through EDQM Helpdesk.

* You can subscribe to 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.
New texts for comment,
List of texts adopted at the EPC
Publication schedule
Comments about texts revised in the 10th edition

Draft harmonised texts for comment
PDG state of work

EDQM News
Events
Pharmeuropa 32.1: the issue is now complete (public enquiry until 31 March 2021)
Pharmeuropa 31.4: draft texts are now found in Pharmeuropa archives
Comments concerning revised texts published in Supplement 10.2
You have the possibility to express opinion in response to an article in Pharmedeuropa Bio & Scientific Notes

**Pharmedeuropa Bio & Scientific Notes and Readers' Tribune**

- **2014**
  - Market to ensure consistent quality of homeopathic products in Europe

- **2013**
  - Quality aspects of homeopathic preparations
  - Quality of TCM drugs and TCM products

- **2012**
  - A consideration of the analytical requirements for finding herbal drugs used to produce herbal drug preparations
  - Monographs on medicines: GMP and Production statement?
  - Molecular weights under discussion?

- **2011**
  - Re-examination of the general monographs on herbal drugs and herbal drug preparations with reference to monographs on traditional Chinese herbal ingredients
  - Comments on the articles of Dr. Keith Hellier on European Pharmacopoeia monographs on extracts
  - Inquiries and changes regulatory requirements in the EU

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**Pharmedeuropa Online**

**Texts for Comment**

**Pharmedeuropa Bio & Scientific Notes**

**Pharmedeuropa Archives**

**What's New?**

- Ph. Eur. Section 3. Materials for containers: clarification of legal status
- Examples of validation protocols of the alternative microbiological methods according to chapter 5.1.6. Alternative methods for control of microbiological quality
- Reverse osmosis in Ph. Eur. monograph water for injections (p166)
- Bacterial endotoxins: European Pharmacopoeia policy (revised February 2015)
- Response and correction factors in monographs of the European Pharmacopoeia
- Homopathic preparations: changes to titles of monographs
- Veterinary vaccines: harmonisation with ICH Guidelines D1 and D4
10th edition
Work of the Ph. Eur., procedures
Procedure to comment, addresses of NA, etc.

Provides access to other EDQM publications such as:
Standard terms, European Paediatric Formulary,
Proceedings of International Conferences,
Ph. Eur. technical guides...
Keep in touch – Don’t miss an opportunity to comment on draft texts

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Ph. Eur. ONLINE

• New platform for the 10th edition

• Ph. Eur. electronic version is part of a new publication platform which includes the PaedForm website and Pharmeuropa

• 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).
Ph. Eur. ONLINE

- 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, Pharmeuropa)

NEW possibility
- use the arrows.
- New layout to access General Notices & General monographs.

NEW possibility of advanced queries and saving them.
- Query in 6 texts: contains "Fluorescence" & "methylene".

- possible to save queries

- 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
  - April 2020: 10.0
  - July 2020: 10.1
  - January 2021: 10.2, etc.

- Ph. Eur. Archives will remain in PDF format
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KNOWLEDGE DATABASE

• How to connect?

Direct link from electronic Ph. Eur.

2D code in print edition

PARACETAMOL

C,H,NO,

DEFINITION
N-(4-Hydroxyphenyl)acetamide.
Content: 99.0 per cent to 101.0 per cent (dried substance).
CHARACTERS
Appearance: white or almost white, crystalline powder.
Solubility: sparingly soluble in water, freely soluble in ethanol (96 per cent), very slightly soluble in methylene chloride.
The monograph has been authorised but work has not started yet.

Work has started (first draft).

The monograph has been submitted for adoption to the European Pharmacopoeia Commission.

The monograph has been adopted.

The monograph is about to be published, or has been published.

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

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.
KNOWLEDGE DATABASE

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 O) and only a mixed melting point now described.
Related substances: new LC to take into account additional impurities.

EDITION 9.0
Heavy metals: text 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.

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.
Thank you for your attention

Stay connected with the EDQM

EDQM Newsletter: https://go.edqm.eu/Newsletter
LinkedIn: https://www.linkedin.com/company/edqm/
Twitter: @edqm_news
Facebook: @EDQM_Council_of_Europe