Knowledge Database: How to read the table

The updated sections are highlighted in blue.

- **NEW: Status**: "in use" the monograph is published in the European Pharmacopoeia, "elaboration" monograph is under elaboration and has not yet been published.

- **Monograph number**: the unique number allocated to a monograph or a general method as soon as it is authorised for elaboration. This number never changes, contrary to the titles and should be used as a unique and unambiguous reference to a text of the European Pharmacopoeia.

- **English, French and Latin names**: those are the monograph or general methods titles as they are currently approved by the European Pharmacopoeia Commission. **They may differ from the titles currently published in the Pharmacopoeia**, especially for monographs undergoing a revision. In case of any doubt, please refer to the monograph number.

- **Published in Supplement:** starting from 6.0, the first publication in the European Pharmacopoeia of the most recent version of the text in terms of technical content (i.e. no technical revision or correction has been made since this publication, but editorial modifications may have been made). The first digit is the edition number and the second is the supplement number (0 represents the main volume of the edition in question).

PLEASE NOTE: the number given refers to the English version of the European Pharmacopoeia, and while this usually applies equally to the French version, a divergence may arise where a text is corrected in one language only; users of the French version of the European Pharmacopoeia are advised to refer to the index of the latest supplement.

PLEASE NOTE: from the 7th Edition, if a text has not undergone a technical revision for a new edition, the version date published in the previous edition will be kept in order to improve traceability.

- **NEW: Work in progress**: the boxes in light blue indicate whether a monograph is currently being elaborated or undergoing revision (Technical revision or Minor revision) and provide relevant information to the work on-going: current State of work and Pharmeuropa issue. Under "Description" if it is a revision, information on the test(s) revised and/or the reason for revision are provided.

If you are interested in participating to the revision work and if the state of work is 0 or 1 please contact the EDQM through the HelpDesk so that you can be involved in the elaboration/revision process. We welcome your contributions to the work of the European Pharmacopoeia.

- **State of work**: the figures are to be interpreted as follows:

  - 0 the monograph has been authorised but work has not started yet
  - 1 - Draft work has started
  - 2 - Pharmeuropa the monograph has been authorised for publication in Pharmeuropa (see Pharmeuropa number)
  - 3 - COM the monograph has been submitted for adoption to the European Pharmacopoeia Commission
  - 4 - DEF the monograph has been adopted

Please note that texts which are published in Pharmeuropa (step 2 - public enquiry) can be consulted for free by registering on Pharmeuropa online, the procedure on how to comment is here. The supply of individual copies of our documents by fax, e-mail or otherwise, whatever their state of work, is excluded.

- **Pharmeuropa:** the number of the issue of Pharmeuropa into which the draft of the monograph was published.

- **Chromatogram**: Chromatograms supplied with some reference standards:
These are available only if they are mentioned in the related monograph. They are sent to users on an official leaflet with the standards and are also available for download from the online CRS/BRP catalogue.

Chromatograms for information:
if a hyperlink appears in the adjacent cell, a type chromatogram is available for download. It should be stressed that such chromatograms do not constitute a mandatory part of the corresponding monograph. 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.

- **Additional information**: if a hyperlink appears in the adjacent cell, some information is available about the monograph or one of the tests in the monograph. It should be stressed that such information is provided solely for the convenience of the user and **does not constitute a mandatory part of the corresponding monograph**.

- **View 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.

- **NEW: Interchangeable (ICH_Q4B)**: the section reflects the status of the text with regard to the work of:

  - the Pharmacopoeia Discussion Group (PDG), a joint collaboration between the United States Pharmacopeia, the Japanese Pharmacopeia and the European Pharmacopoeia.
  - the International Conference on Harmonisation (ICH) Quality Guideline on Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH (Q4B).

- **International Harmonisation chapter 5.8**: Further information can be found in chapter 5.8 (Pharmacopoeial Harmonisation) of the European Pharmacopoeia.

- **Reference standards**: a list of the reference standard(s) that have to be used to carry out the monograph. For more information, please refer to the most up-to-date version of the monograph as published in the European Pharmacopoeia. This is an excerpt from our online CRS catalogue.

- **Trade names**: certain tests require the use of commercially available reagents, which cannot be described with the required accuracy in the European Pharmacopoeia. This page provides the trade name(s) of the reagent(s) that was (were) **found to be suitable when the monograph was being developed**. This information is provided solely for the convenience of users of the Pharmacopoeia. **It does not imply that these reagents or their suppliers are endorsed or recommended by the European Pharmacopoeia Commission or the Council of Europe, in preference to others of a similar nature which are not mentioned**. The analyst is also to be aware of the fact that some reagents can show significant batch to batch variations for which EDQM cannot be held responsible.

- **CEP**: if certificate(s) of suitability have been granted for the substance in question, their list is shown. This is an excerpt from the online List of CEP.