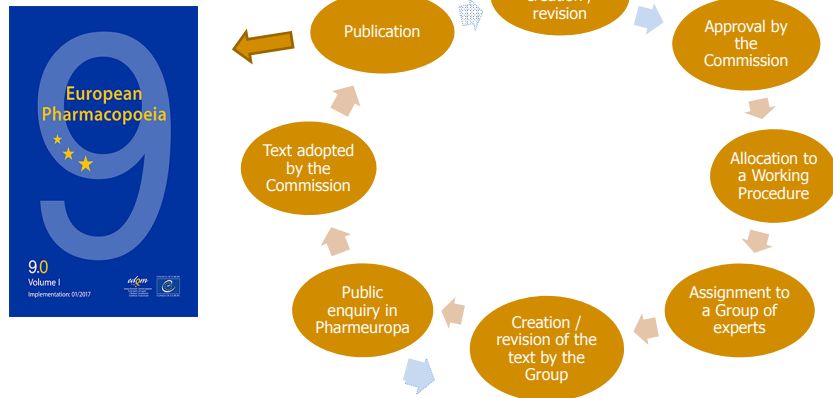


Procedure for new and revised texts

Chair of the Ph. Eur. Commission
Delegation of a member state
Experts, EDQM



Adoption and implementation of texts

1. Adoption by Commission
2. Publication in the Ph. Eur.
3. Implementation 1 year after adoption
(see publication schedule available on website)

Overall timescale: minimum 2 years

Including 5 months for public enquiry and at least 6 months between adoption and publication

Commission Sessions		Edition Supplement	Publication schedule	Implementation date
Session No.	Date			
153	November 2015	9 th Edition	July 2016	1 January 2017
154	March 2016	9.1	October 2016	1 April 2017
155	June 2016	9.2	January 2017	1 July 2017
156	November 2016	9.3	July 2017	1 January 2018
157	March 2017	9.4	October 2017	1 April 2018
158	June 2017	9.5	January 2018	1 July 2018
159	November 2017	9.6	July 2018	1 January 2019
160	March 2018	9.7	October 2018	1 April 2019
161	June 2018	9.8	January 2019	1 July 2019
162	November 2018	10 th Edition	July 2019	1 January 2020



162	November 2018	10 th Edition	July 2019	1 January 2020
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Information about ongoing work programme

Additions announced on:

- EDQM website
<http://www.edqm.eu/en/european-pharmacopoeia-work-programme-607.html>
- Pharmeuropa Online
<http://pharmeuropa.edqm.eu/home/> under “*useful information*”

Status found in knowledge database

<https://www.edqm.eu/en/where-find-knowledge-database>

News: April 2017

Revision: Erythromycin ethylsuccinate (05/2017:0274)

« Back

EUROPEAN PHARMACOPOEIA MONOGRAPH | NEWS | 03 APRIL 2017 | STRASBOURG, FRANCE

Pending completion of the review of the related substances test published in Ph. Eur. 9.0 by the Ph. Eur. group of experts, and to ensure a continuing supply of erythromycin ethylsuccinate active substance to the European markets, a revised monograph has been prepared as an interim measure and is effective as of **01 May 2017**. The monograph has been revised to replace the test for related substances published in Ph. Eur. 9.0 with the test in the monograph published in Ph. Eur. 8.0, and the impurities section has therefore been adapted accordingly; the rest of the monograph remains unchanged.

This revised monograph is available online as of Supplement 9.1 and in the other formats, i.e. print and downloadable, as of Supplement 9.3.

This change has been endorsed and carried out in the form of a Resolution of the European Committee on Pharmaceuticals and Pharmaceutical Care, with a view to its rapid implementation outside the normal publication cycle of the European Pharmacopoeia.

Any future changes or revisions of this monograph would be published in Pharmeuropa for public consultation and comment according to the normal procedure. The EDQM encourages all interested parties to provide input at that time.

How can manufacturers request revision?

Europe: via National Pharmacopoeia Authority
(address list on EDQM website and in Pharmeuropa)

Outside Europe: contact EDQM which will refer the matter to a group of experts or to the Commission

Make clear what needs revising and if possible make a concrete proposal

Collaboration with industry essential

Collaboration with
Industry is essential
for having meaningful
monographs



Data is needed for work with new monographs and revisions

- Work can only be undertaken if the request is backed up by sufficient data
- Provide batch data, sample chromatograms, etc.
- Supply validated methods and samples, notably for all impurities controlled in the test for related substances

Co-operation and committed experts needed

720 experts from the Ph. Eur. members states and observers in 20 permanent expert groups and about 35 working parties

- Industry
- Regulators
- Academia



In many groups lab resources is needed

Implementation of the ICH Q3D guideline on elemental impurities

- **General chapter 5.20 Elemental impurities:** reproduces parts of the Scope and the Introduction sections of the ICH Q3D guideline and refers to the guideline which can be found in full on the ICH website
- **General monograph on Pharmaceutical preparations (2619):** refers to chapter 5.20, rendering it —and by extension the ICH Q3D guideline — legally binding
- **General monograph on Substances for pharmaceutical use (2034):** introduces requirements for the control of elemental impurities intentionally added during production and explains the absence of a test for elemental impurities from individual monographs except for special cases (see paragraph on specific tests below)
- **General method 2.4.20 Determination of elemental impurities:** provides guidance for aspects of method development such as sample preparation and method validation for the determination of elemental impurities.

New challenges: Control of impurities

- Elemental impurities ICH Q3D
 - Requirement are set on finished products
- Genotoxic impurities ICH M7
 - New approach
 - Measurement of low concentrations need sophisticated analytical methodology
 - Pyrrolizidine alkaloids in substances and preparations of herbal origin

- A trend in industry is to perform assay using liquid chromatography
- In the European Pharmacopeia now a number of assays using titration have been replaced by liquid chromatography

- Liquid chromatographic methods with high selectivity introduced
 - Core shell columns (can be used in any LC-system)
 - UPLC columns



Future trends; New technologies

- New analytical techniques are introduced in the Method chapters
- Techniques that are likely to be used in a higher extent in the future
 - UPLC
 - LC/MS/MS
 - NMR
 - Chemometrics

CEP facilitate development

- CEP important for the development of the European Pharmacopeia
- Monographs are based on approved specifications
- Information from CEP having a different specification as compared to the existing monograph will facilitate development



Relationship Ph. Eur. - CEP

- Ph. Eur. monographs are necessary to get a CEP, therefore establishing new monographs in a timely manner is important, for the CEP procedure and for applicants
- In case where the monograph(s) to which the certificate refers **is revised** by the European Pharmacopoeia Commission, the manufacturer has to show compliance with the new requirements. The Certification Secretariat will ensure that the quality of the substance still meets the criteria of the revised monograph(s). The Secretariat will then either **send a revised certificate** to the holder or **ask him to update its dossier** in compliance with the revised monograph(s).

Relationship Ph. Eur. - CEP

- The manufacturer requests a certificate by submitting a copy of a dossier according to the CTD format and including the relevant part of the Quality Overall Summary (QOS)
- The assessors examine the dossier submitted and prepare a report in three parts:
 - Report A or “Confidential report”
 - Report B or “request for revision of the monograph”
 - Report C or “Comments for the inspectors”.

- Report B or “request for revision of the monograph”, when updating of the monograph is requested. This report contains the information that the relevant Group of Experts of the European Pharmacopoeia needs to update the monograph which has been shown to be inadequate. It is prepared so as not to divulge the confidential information in the dossier. This part of the report shall be sent to the manufacturer prior to its transmission to the expert group concerned.
- The expert group evaluates the request of revision and if it is found to be relevant the revision work starts
- Often new impurities, specified and unspecified

- CEP facilitates the development of Ph. Eur.
- CEP and Ph. Eur. has a well working relationship
- Input from CEP is highly appreciated by Ph. Eur.