



How to develop/revise an Excipient Ph Eur monograph : an industry experience

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Monograph elaboration: Ph Eur versus USP flow chart



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How to interact/participate in Ph Eur work ?



Via National Health Authority

Monograph proposal

Via Helpdesk Tool:
+ form :
"REQUEST FOR REVISION
OF A MONOGRAPH OR
GENERAL CHAPTER "

Comments

**Non Ph Eur
members states**

- 4 issues/year
(JAN/APR/JULY/OCT)
- 90 days period
- Free access:
<http://pharmeuropa.edqm.eu>



How to interact/participate in Ph Eur work ?



Non Ph Eur
members states



Experts



Some tools : TECHNICAL GUIDES

Download: <http://www.edqm.eu/en/technical-guides-589.html>

Technical Guide

for the elaboration of monographs

European Pharmacopoeia

European Directorate for the Quality of Medicines & HealthCare

This document is a guidance for the authors of monographs and also a means of communicating to the users of the European Pharmacopoeia, especially industry, licensing authorities and official medicines control laboratories, the principles for the elaboration of monographs.

Since the principles applied and guidance given for the elaboration of monographs should be the same as those applied by licensing authorities, the Technical Guide may also serve as a guideline in the elaboration of specifications intended for inclusion in licensing applications.



Some tools: PHARMEUROPA

<http://pharmeuropa.edqm.eu/home/>

Pharmeuropa Online

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European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

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Texts for comment

Pharmeuropa Bio & Scientific Notes

Pharmeuropa archives

What's new? Pharmacopoeial harmonisation Readers' tribune Useful information Publications

Texts for comment: 9 draft(s) added in the last week

EDQM News

Events

Comments concerning revised texts published in Supplement 8.3

Equivalence testing in the European Pharmacopoeia

Pharmeuropa Bio & Scientific notes 2014: Molecular size distribution method using a GMPW_{XL} column

First draft finished product monograph with chemically defined active substance published for comment

Supplement 8.3: list of texts published

Pharmeuropa 26.2: the issue is now complete (public enquiry until 30 June 2014)

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Deadline: 30.06.2014
Pharmeuropa - Issue 26.2

FR Document in French PDF How to comment

Reference: PA/PH/Exp. CEL/T (08) 9 ANP 1R 1

NOTE ON THE MONOGRAPH 2
 This draft corresponds to Stage 4 rev. 3 within the Pharmacopoeial harmonisation process (Ph. Eur., JP, USP). The coordinating pharmacopoeia is the USP. The original text submitted to the Pharmacopoeial Discussion Group is published in the Pharmacopoeial harmonisation section. 3
 This monograph is a new one (prospective harmonisation). A draft text has already been published in Pharmeuropa 21.1. Compared to the latter text, the following changes are proposed: a third identification is proposed, no test for heavy metals is included, a slightly modified assay method is proposed which is very similar to that implemented in the harmonised monograph on Methylcellulose (0345). 4 XXXX:2083 5

HYDROXYPROPYLCELLULOSE, LOW-SUBSTITUTED 6
 Hydroxypropylcellulosum substitutum humile 7

DEFINITION 8
 Low-substituted O-(2-hydroxypropylated) cellulose. 9

- for manufacturers and other interested parties from **non-member states of the Ph. Eur. Convention**, and for **multinational** interested parties:
 - preferably via the national pharmacopoeia authority of the member state where the product is authorised;
 - in cases where comments are submitted to the EDQM Helpdesk, please indicate the member state(s) where the product is authorised



Commission Sessions		8 th Edition Supplements	Publication Schedule	Implementation Date
Session N°	Date			
–	–	8th Edition	15 July 2013	1 Jan. 2014
145	Mar. 2013	8.1	1 Oct. 2013	1 Apr. 2014
146	June 2013	8.2	1 Jan. 2014	1 July 2014
147	Nov. 2013	8.3	1 July 2014	1 Jan. 2015
148	Mar. 2014	8.4	1 Oct. 2014	1 Apr. 2015
149	June 2014	8.5	1 Jan. 2015	1 July 2015
150	Nov. 2014	8.6	1 July 2015	1 Jan. 2016
151	Mar. 2015	8.7	1 Oct. 2015	1 Apr. 2016
152	June 2015	8.8	1 Jan. 2016	1 July 2016
153	Nov. 2015	9th Edition	15 July 2016	1 Jan. 2017

