

The hologram on the front cover of this Supplement and the EDQM Publication ID (EPID) given below certify that the publication you have purchased is legally licensed from the European Directorate for the Quality of Medicines & HealthCare (EDQM), Strasbourg, France. In order to benefit from our user support, or if you have any concerns about the authenticity of this publication, please visit our website

**<http://www.edqm.eu>**

where you can register your copy and validate the EPID number.

┌

┐

└

┘

# EUROPEAN PHARMACOPOEIA - SUPPLEMENT 6.3 TO THE 6<sup>th</sup> EDITION

published 10 June 2008

The 6<sup>th</sup> Edition of the European Pharmacopoeia consists of volumes 1 and 2 of the publication 6.0, and Supplements 6.1 to 6.3. These will be complemented by **non-cumulative supplements** that are to be kept for the duration of the 6<sup>th</sup> Edition. 3 supplements will be published in each of the years 2008 and 2009. A cumulative list of reagents will be published in supplements 6.4 and 6.7.

To use the 6<sup>th</sup> Edition correctly, make sure that you have all the published supplements and consult the index of the most recent supplement to ensure that you use the latest versions of the monographs and general chapters.

## EUROPEAN PHARMACOPOEIA - ELECTRONIC VERSION

The 6<sup>th</sup> Edition is also available in an electronic format (CD-ROM and online version) containing all of the monographs and general chapters found in the printed version. With the publication of each supplement the electronic version is replaced by a new, fully updated, cumulative version.

In addition to the official English and French online versions, a Spanish online version (5<sup>th</sup> Edition) is also available for the convenience of users.

## PHARMEUROPA

### Quarterly Forum Publication

Pharmeuropa contains preliminary drafts of all new and revised monographs proposed for inclusion in the European Pharmacopoeia and gives an opportunity for all interested parties to comment on the specifications before they are finalised. Pharmeuropa also contains information on the work programme and on certificates of suitability to monographs of the European Pharmacopoeia issued by the EDQM, and articles of general interest. Pharmeuropa is available on subscription from the EDQM. The subscription also includes Pharmeuropa Bio and Pharmeuropa Scientific Notes (containing scientific articles on pharmacopoeial matters). Pharmeuropa Online is also available as a complementary service for subscribers to the printed version of Pharmeuropa.

## INTERNATIONAL HARMONISATION

See the information given in chapter 5.8. *Pharmacopoeial Harmonisation*.

## WEBSITE

<http://www.edqm.eu>

<http://www.edqm.eu/store> (for prices and orders)

## HELPDESK

To send a question or to contact the EDQM, use the HELPDESK, accessible through the EDQM website (visit [http://www.edqm.eu/site/FAQ\\_Helpdesk-521.html](http://www.edqm.eu/site/FAQ_Helpdesk-521.html)).

## KNOWLEDGE

Consult KNOWLEDGE, the new free database at <http://www.edqm.eu> to obtain information on the work programme of the European Pharmacopoeia, the volume of Pharmeuropa and of the European Pharmacopoeia in which a text has been published, trade names of the reagents (for example, chromatography columns) that were used at the time of the elaboration of the monographs, the history of the revisions of a text since its publication in the 5<sup>th</sup> Edition, representative chromatograms, the list of reference standards used, and the list of certificates granted.

## COMBISTATS

CombiStats is a computer program for the statistical analysis of data from biological assays in agreement with chapter 5.3 of the 6<sup>th</sup> Edition of the European Pharmacopoeia. For more information, visit the website (<http://www.edqm.eu/combistats>).

Members of the European Pharmacopoeia Commission: Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, 'the former Yugoslav Republic of Macedonia', Turkey, United Kingdom and the European Union.

Observers to the European Pharmacopoeia Commission: Albania, Algeria, Australia, Belarus, Brazil, Canada, China, Georgia, Israel, Madagascar, Malaysia, Moldova, Morocco, Republic of Kazakhstan, Russian Federation, Senegal, Syria, Tunisia, Ukraine, United States of America and WHO (World Health Organisation).



**How to contact us**  
*Information and orders* **Internet: <http://www.edqm.eu>**

**European Directorate for the Quality of Medicines & HealthCare (EDQM)**  
 Council of Europe - 7 allée Kastner  
 CS 30026, F-67081 STRASBOURG, FRANCE  
**Tel:** +33 (0)3 88 41 30 30\*  
**Fax:** +33 (0)3 88 41 27 71\*  
 \*Do not dial 0 if calling from outside of France

**Correspondence** ..... Via the online HELPDESK ([http://www.edqm.eu/site/FAQ\\_Helpdesk-521.html](http://www.edqm.eu/site/FAQ_Helpdesk-521.html))

**How to place an order**  
 Publications ..... <https://www.edqm.eu/store>  
 Reference standards ..... <http://www.edqm.eu>  
 Reference standards online order form ..... [http://www.edqm.eu/site/EDQM\\_Reference\\_standards-649.html](http://www.edqm.eu/site/EDQM_Reference_standards-649.html)  
 Further information, including answers to the most frequently asked questions regarding ordering, is available via the HELPDESK.

**All other matters** ..... [info@edqm.eu](mailto:info@edqm.eu)  
 All reference standards required for application of the monographs are available from the EDQM.  
 A catalogue of reference standards is available on request; the catalogue is included in the Pharmeuropa subscription;  
 it can also be consulted on the EDQM website.

# EUROPEAN PHARMACOPOEIA

SIXTH EDITION

Supplement 6.3



# EUROPEAN PHARMACOPOEIA

SIXTH EDITION

Supplement 6.3

*Published in accordance with the  
Convention on the Elaboration of a European Pharmacopoeia  
(European Treaty Series No. 50)*



Council of Europe  
Strasbourg

The European Pharmacopoeia is published by the Directorate for the Quality of Medicines & HealthCare of the Council of Europe (EDQM).

© Council of Europe, 67075 Strasbourg Cedex, France - 2008

All rights reserved. Apart from any fair dealing for the purposes of research or private study, this publication may not be reproduced, stored or transmitted in any form or by any means without the prior permission in writing of the publisher.

ISBN: 978-92-871-6312-7