# **EDQM**

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2016

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## THE EUROPEAN PHARMACOPOEIA COLLECTION

### NEW: 9th Edition of the European Pharmacopoeia: earliest access to the European quality standards

### **Description:**

- The European Pharmacopoeia (Ph. Eur.) is continuously updated, with new and revised texts published three times a year.
- Available in 3 formats with direct access to the Knowledge database:
  - ▶ **Book**: an initial base edition in three volumes (9.0) plus 8 individual supplements (9.1 to 9.8) (English or French)
  - ► Cumulative online version: responsive design, compatible with tablets and smart devices: http://online.edqm.eu/
  - ► USB stick: easy access to the cumulative Ph. Eur. version while on the move
  - ► Packages: special offers are available for customers interested in more than one format.
- Advantages of the electronic format (online and USB):
  - ▶ Bilingual (English and French) and cumulative supplements
  - ► Access to online archives of the European Pharmacopoeia
  - ► Full search functions and links to monographs, general methods and reagents
  - ► Changes (inserted or deleted texts) indicated in both HTML and PDF versions
  - Possibility of adding RSS feeds for specific queries.

### Product details - ISBN/ISSN

Book subscription 9th Edition 2016 (volumes 9.0-9.2) – English version ISBN/ISSN: 978-92-871-8133-6

Online subscription 9th Edition 2016 (volumes 9.0-9.2) – Bilingual ISBN/ISSN: 978-92-871-8138-1

USB Stick subscription 9th Edition 2016 (volumes 9.0-9.2) – Bilingual ISBN/ISSN: 978-92-871-8137-4

### Other products of interest:

- Online Knowledge Database for questions on a substance or text in the Ph. Eur.: https://go.edqm.eu/knowledge
- Technical Guides and the European Pharmacopoeia Style Guide are available free of charge here: https://go.edqm.eu/techguides
- CombiStats<sup>™</sup>: statistical analysis software computer program for calculations in accordance with chapter 5.3 of the European Pharmacopoeia.

For further information and a free demonstration, visit: https://www.edqm.eu/combistats

### PHARMEUROPA ONLINE

## Pharmeuropa Online: the Ph. Eur. online forum. Available FREE of charge!



#### **Contents:**

- Ph. Eur. texts for comment:
  - ▶ Public inquiries on draft Ph. Eur. monographs and general texts, or on matters of general policy
  - ▶ Published continuously, with 4 deadlines for comments per year.
- Pharmeuropa Bio & Scientific Notes

News in the biological standardisation area and scientific articles linked to the work of the Ph. Eur.

- Pharmeuropa archives
  - ▶ 29 years of electronic archives of Pharmeuropa.

### **Additional features:**

- ► Latest official announcements on newly adopted monographs
- ▶ Latest news on Pharmacopoeial Harmonisation
- ► A readers' tribune
- ▶ Notification on texts or groups of texts for comment.

### **Practical information:**

Register to get access to the online version: https://go.edqm.eu/pharmeuropahttp://pharmeuropa.edqm.eu/

### Product details - ISBN/ISSN

Online PHARMEUROPA ISSN: 2225-2339

Online PHARMEUROPA Bio & Scientific Notes: ISSN: 2075-2504

## CERTIFICATION OF SUITABILITY TO THE EUROPEAN PHARMACOPOEIA (CEP)

### **Description:**

- ➤ Scope: active substances or excipients covered by a monograph in the European Pharmacopoeia, including herbal products; any product with TSE risk
- Centralised evaluation of quality dossiers (EU legislation for medicinal products)
- ► CEPs replace the detailed data in marketing authorisation applications (MAA) and facilitate the management of MAA
- ► CEPs are recognised in all 37 Ph. Eur. Member States and beyond (e.g. Australia, Canada, Singapore, South Africa)
- ▶ Procedure complemented by a risk-based inspection programme of manufacturing sites.

### **Practical information:**

For more information on the Certification procedure: https://go.edqm.eu/CEP

To access the Certification Database: https://go.edqm.eu/cepdatabase

### **STANDARD TERMS DATABASE**

### **Available FREE of charge!**

### **Description:**

- Database containing standard terms for pharmaceutical dose forms, routes and methods of administration, containers, closures, delivery devices, combined terms and patientfriendly terms for medicines for human and veterinary use.
- ► European Union Guideline status: must be used in marketing authorisation applications for medicines (i.e. the Application Form and the Summary of Product Characteristics (SmPC)).
- ▶ 870 individual terms and over 23 000 translations in 33 languages.

### **Practical information:**

For more information on the Standard Terms database: https://go.edqm.eu/standardterms

Free access after registration: www.edqm.eu/register Online version: https://standardterms.edqm.eu

### **ORDERING EDOM PUBLICATIONS**

Orders can be sent to the EDQM via:

- ► Internet: www.edqm.eu/store
- ► E-mail: orders@edqm.eu with the order form as an attachment
- ► Fax to Sales Section at +33 (0)3 88 41 27 71

Details on prices and availability can be found on the EDQM Store under each product item.

## PUBLICATIONS ON PHARMACEUTICAL CARE

## Policies and practices for a safer, more responsible and cost-effective health system (2012)

Available to download free of charge (PDF format) from: https://go.edqm.eu/pharmacare

## Pharmaceutical Care: Where do we stand – Where should we go?

Product details - ISBN/ISSN

Print English version – ISBN: 978-92-871-6712-5

## PUBLICATIONS ON COSMETICS & FOOD CONTACT MATERIALS

### Safe Cosmetics for Young Children – 1st Edition (2012)

### Product details - ISBN/ISSN

Print English version – ISBN: 978-92-871-7360-7

## Metals and alloys used in food contact materials and articles – 1st Edition (2013)

### Product details - ISBN/ISSN

Print English version – ISBN: 978-92-871-7703-2



## PUBLICATIONS ON BLOOD TRANSFUSION & ORGAN, TISSUES AND CELLS TRANSPLANTATION

### As of 1/1/2016 new editions available online FREE of charge!

All previous guides are available in English: print and online (PDF and EPUB formats).

Guide to the preparation, use and quality assurance of blood components – 18th Edition (2015)

### Product details - ISBN/ISSN

Print English version – ISBN: 978-92-871-8071-1.

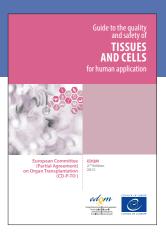
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## Guide to the quality and safety of organs for transplantation – 5th Edition (2013)

#### Product details - ISBN/ISSN

Print English version – ISBN: 978-92-871-7638-7



### Guide to the quality and safety of tissues and cells for human application – 2nd Edition (2015)

#### Product details - ISBN/ISSN

Print English version – ISBN: 978-92-871-8126-8

### **Practical information:**

http://tots.edgm.eu

To access, clients must register online: www.edqm.eu/register

## COUNCIL OF EUROPE RESOLUTIONS, RECOMMENDATIONS, CONVENTIONS AND REPORTS

- ► Blood and Blood Components Council of Europe Resolutions, Recommendations and Convention (1st Edition)
- ➤ Organs, Tissues and Cells: Safety, Quality and Ethical Matters Concerning Procurement, Storage and Transplantation (2nd Edition).

### **Practical information:**

publications available free of charge in PDF format from: https://go.edqm.eu/BTg – https://go.edqm.eu/OTg

### PUBLICATIONS ON COMBATTING COUNTERFEIT MEDICINES

### **Description:**

- ➤ Open minds, free minds: Psycho-pedagogical concept guide for teachers (2015)
- ► A strategic approach to assist states in protecting the health of their citizens (2013)
- ► Counterfeit Medicines: Facts and practical advice (2011)

### **Practical information:**

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- 1 Colourful areas
- 2 Mirrored mini-text
- 3 Colourful letters and stars
- 4 Lens effect



## EUROPEAN PHARMACOPOEIA REFERENCE STANDARDS (RS)

### 75 new RSs established in 2015

A collection of 2708 items available: chemical, herbal and biological reference standards and materials and reference spectra.

- ▶ Ph. Eur. Reference Standards are necessary for the application of Ph. Eur. monographs
- ► The EDQM laboratory establishes and monitors the fitness for use of Ph. Eur. Standards and Preparations
- ► Establishment reports are adopted by the European Pharmacopoeia Commission.

### Consult the online catalogue (updated daily): http://crs.edqm.eu

### **Practical information:**

- ➤ Search by catalogue code, reference standard name, monograph number or CAS number to quickly locate the standard you need
- ► Batch Validity Statement (BVS) for reference standards enables users to verify, at time of use, the validity of batches supplied
- ➤ Safety data sheets (SDS) and leaflets (where applicable) can be accessed via the Reference Standard catalogue: http://crs.edgm.eu/

## WHO INTERNATIONAL STANDARDS FOR ANTIBIOTICS (ISA) AND WHO INTERNATIONAL CHEMICAL REFERENCE SUBSTANCES (ICRS)

### The EDQM distributes WHO ISA and WHO ICRS:

- ▶ ISA: : reference substances for use as primary standards in microbiological testing of antibiotics. ISA can also be used by regional or national pharmacopoeias to establish secondary standards.
- ▶ ICRS: primary chemical reference substances established on the advice of the WHO Expert Committee on Specifications for Pharmaceutical Preparations. They are supplied for use in physical and chemical tests and assays described in the International Pharmacopoeia or other WHO quality assurance documents.

### **Practical information:**

➤ Safety data sheets (SDS), leaflets and study reports (only for ISA) available online (PDF format):

https://go.edqm.eu/ISAen https://go.edqm.eu/ICRSen

### ORDERING EDQM REFERENCE STANDARDS, ISA and ICRS

Details of prices, availability and the terms and conditions of supply of reference standards can be found in the relevant online catalogues:

http://crs.edqm.eu https://go.edqm.eu/isadb https://go.edqm.eu/icrsdb

Orders can be sent to the EDQM:

- ► Via the internet using the online order form:
  - For CRS: https://go.edqm.eu/RSorder
  - For ISA: https://go.edgm.eu/ISAorder
  - For ICRS: https://go.edgm.eu/ICRSorders
- ► By e-mail to orders@edqm.eu with you official order form attached
- ▶ By fax to Sales Section at +33 (0)3 88 41 27 71.

Payment can be made by bank transfer or credit card via the internet: www.edqm.eu/store



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### How to contact the EDQM:

By phone: +33 (0)3 88 41 30 30\* By fax: +33 (0)3 88 41 27 71\*

Questions may be sent to the EDQM via the HelpDesk user support available on our website: www.edqm.eu/hd

### **Postal address:**

European Directorate for the Quality of Medicines & HealthCare (EDQM)

7 allée Kastner, CS 30026,

F-67081 Strasbourg France

<sup>\*</sup> Omit the 0 if calling from outside France.

Council of Europe.

This publication presents an overview of the Products and Services available in 2016 from the European Directorate for the Quality of Medicines & HealthCare,

### www.edqm.eu

The Council of Europe is the continent's leading human rights organisation. It comprises 47 member states, 28 of which are members of the European Union. The European Directorate for the Quality of Medicines & HealthCare (EDQM) is a directorate of the Council of Europe. Its mission is to contribute to the basic human right of access to good quality medicines and healthcare and to promote and protect public health.



