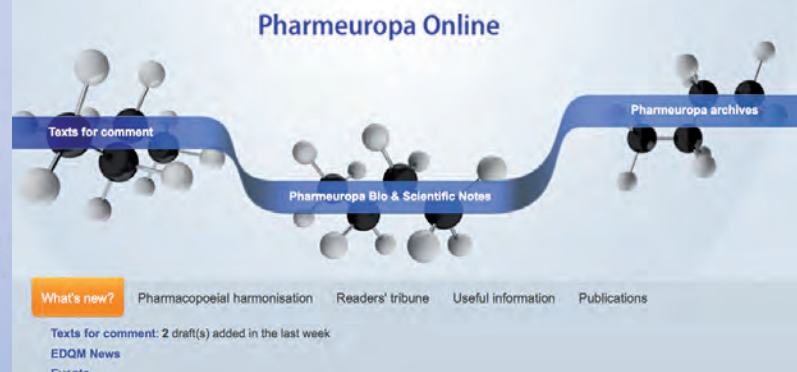


EDQM

Overview of our products and services



2018

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EUROPEAN PHARMACOPOEIA (Ph. Eur.) 2019 UPDATE (9.6-9.8)

The earliest access to the European quality standards

Description:

Legally binding in 38 European countries and applied in more than 100 countries worldwide.

Provides new and revised texts.

Delivers crucial information for the European markets earlier than any other Pharmacopoeia.

Available in online, print and downloadable formats with a number of packages available.

All versions allow free access to the "Knowledge" Database and the Online Archives.

Special conditions available for multiple and unlimited online licences. Do not hesitate to contact the EDQM for a quotation.

| Commission Sessions | | Edition/ Supplement | Publication schedule | Corrections to be taken into account as soon as possible and not later than | Implementation date |
|---------------------|---------------|--------------------------|-------------------------|---|------------------------|
| Session No. | Date | | | | |
| 153 | November 2015 | 9 th Edition | July 2016 | 31 August 2016 | 1 January 2017 |
| 154 | March 2016 | 9.1 | October 2016 | 30 November 2016 | 1 April 2017 |
| 155 | June 2016 | 9.2 | January 2017 | 28 February 2017 | 1 July 2017 |
| 156 | November 2016 | 9.3 | July 2017 | 31 August 2017 | 1 January 2018 |
| 157 | March 2017 | 9.4 | October 2017 | 30 November 2017 | 1 April 2018 |
| 158 | June 2017 | 9.5 | January 2018 | 28 February 2018 | 1 July 2018 |
| 159 | November 2017 | 9.6 | July 2018 | 31 August 2018 | 1 January 2019 |
| 160 | March 2018 | 9.7 | October 2018 | 30 November 2018 | 1 April 2019 |
| 161 | June 2018 | 9.8 | January 2019 | 28 February 2019 | 1 July 2019 |
| 162 | November 2018 | 10 th Edition | July 2019 | 31 August 2019 | 1 January 2020 |



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CombiStats™: statistical analysis software computer program for calculations in accordance with chapter 5.3 of the European Pharmacopoeia.

Available in online format with an annual licence.

Product details:

<https://go.edqm.eu/combistats>



Pharmeuropa Online: the Ph. Eur. free forum
Help us to shape the future Pharmacopoeia

Description:

Ph. Eur. texts for comment: 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: free access to 30 years of electronic archives.

Product details:

<https://go.edqm.eu/pharmeuropa>

Other products of interest:

Online Knowledge Database for information on a substance or text in the Ph. Eur.:

<https://go.edqm.eu/knowledge>

Technical Guides and the Ph. Eur. Style Guide are available here: <https://go.edqm.eu/techguides>

Standard terms database
Free resource to be used in Marketing Authorisation dossiers

Description:

977 individual concepts and over 27 000 translations in 34 languages for pharmaceutical dose forms, routes and methods of administration, containers, closures, delivery devices, units of presentation, combination terms and patient-friendly 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)).

Product details:

<https://go.edqm.eu/standardterms>





REFERENCE STANDARDS (RS)

Discover the 70 new Ph. Eur. RSs established in 2017

Description:

Over 2800 RS items available: chemical, herbal and biological reference standards and materials and reference spectra.

New: 4 elemental impurity chemical reference standards (lead solution CRS, cadmium solution CRS, mercury solution CRS and arsenic solution CRS).

Necessary for the application of Ph. Eur. monographs.

Carefully established and monitored by the EDQM laboratory.

Practical information:

Online RS Catalogue updated daily: RSs are searchable by code, name, monograph number or CAS number to quickly locate the standard you need. Including RS Batch Validity Statement (BVS) enabling users to verify, at time of use, the validity of batches supplied.

Includes downloadable Safety Data Sheets (SDS) and leaflets (where applicable).

Product details: <http://crs.edqm.eu/>



WHO International Standards for Antibiotics (ISA) and Who International Chemical Reference Substances (ICRS)

Description:

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. 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:

The EDQM distributes WHO ISA and WHO ICRS.

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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>



CERTIFICATION OF SUITABILITY TO THE EUROPEAN PHARMACOPOEIA (CEP)

Make a difference to your business

Description:

For active substances or excipients covered by a monograph in the Ph. Eur., including herbal products; any product with TSE risk.

CEPs replace data in the quality parts of Marketing Authorisation Applications (MAA) and facilitate the management of MAAs.

Centralised evaluation of quality dossiers.

Recognised throughout all 38 Ph. Eur. member states and beyond.

Complemented by a risk-based inspection programme of manufacturing sites.

Practical information:

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<https://go.edqm.eu/CEP>

<https://go.edqm.eu/cepdatabase>

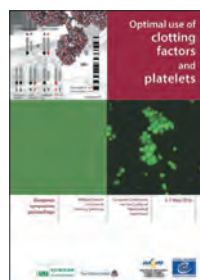
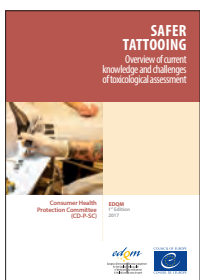
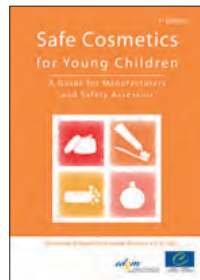
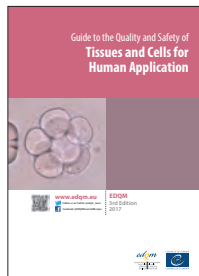


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The EDQM regularly produces publications related to HealthCare activities including:

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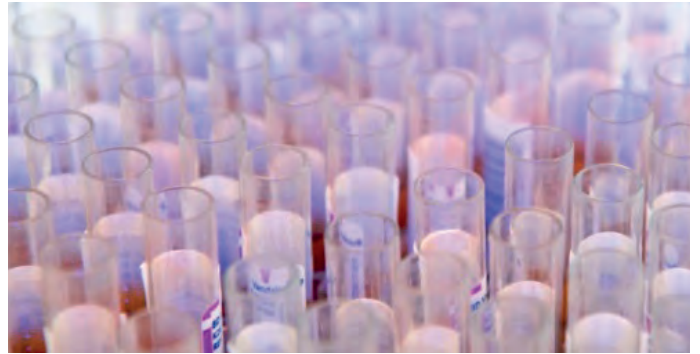
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