



EDQM

Overview
of pharmacopoeia
related products & services

European Pharmacopoeia



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

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<https://store.edqm.eu>



edqm
European Directorate
for the Quality
of Medicines
& HealthCare

Direction européenne
de la qualité
du médicament
& soins de santé

COUNCIL OF EUROPE

CONSEIL DE L'EUROPE

EUROPEAN PHARMACOPOEIA (Ph. Eur.)



Ph. Eur. 11th Edition: the primary source for quality control standards

■ Legally binding in **39 European countries** and used in more than **130 countries** worldwide.

■ Delivers **crucial information** for European markets earlier than any other pharmacopoeia.

■ Continually **updated and modernised** to meet users' needs.

■ Available in **online and print versions**, with direct access to complementary information (EDQM Knowledge Database, Ph. Eur. online archives, etc.).

■ Access to Ph. Eur. **training resources**:
<https://go.edqm.eu/pheurtraining>

■ Dedicated **customer support** through the EDQM's Online FAQs and HelpDesk:
<https://go.edqm.eu/HDpubs>

■ **Prices and product information**:
<https://go.edqm.eu/PhEur11th>

■ **Orders**: <https://store.edqm.eu>

Pharmeuropa Online: free Ph. Eur. user forum

■ Ph. Eur. texts for comment: published regularly, with **four deadlines for comment per year**.

■ *Pharmeuropa Bio & Scientific Notes*: **news in the biological standardisation area** and Ph. Eur. related scientific articles.

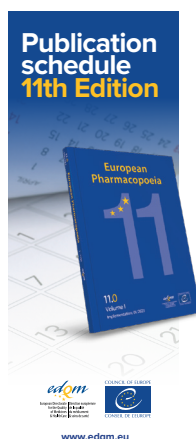
■ *Pharmeuropa* archives: free access to **30 years of electronic archives**.

■ Online platform designed with users in mind: single sign-on, cross-platform, easy navigation, search query management, automatic alerts, etc.:
<https://pharmeuropa.edqm.eu/home>

Other products of interest

■ **CombiStats™**: statistical analysis software for calculations in accordance with chapter 5.3 of the European Pharmacopoeia. Available in **online format with an annual licence**: <https://go.edqm.eu/combistats>

■ **Technical guides and Ph. Eur. style guide** available online: <https://go.edqm.eu/techguides>



COMMISSION SESSION	EDITION/SUPPLEMENT	PUBLICATION SCHEDULE	IMPLEMENTATION DATE
171 / November 2021	11.0	July 2022	1 January 2023
172 / March 2022	11.1	October 2022	1 April 2023
173 / June 2022	11.2	January 2023	1 July 2023
174 / November 2022	11.3	July 2023	1 January 2024
175 / March 2023	11.4	October 2023	1 April 2024
176 / June 2023	11.5	January 2024	1 July 2024
177 / November 2023	11.6	July 2024	1 January 2025
178 / March 2024	11.7	October 2024	1 April 2025
179 / June 2024	11.8	January 2025	1 July 2025
180 / November 2024	12.0	July 2025	1 January 2026

Publication schedule:
<https://go.edqm.eu/PhEurschedule>

REFERENCE STANDARDS (RSs)



European Pharmacopoeia RSs: essential to ensure the quality of medicines

- The only pharmacopoeial source to **verify compliance** with the legal requirements of the European Pharmacopoeia.
- Over 3 000 RSs (chemicals, biologicals and herbals) used in more than **130 countries**.
- **Quality and scientific excellence** in establishing pharmacopoeial RSs.
- Quality management system based on **ISO 9001:2015** and **ISO/IEC 17025:2017** standards, attesting to the **technical expertise** supporting the development of RSs.
- Access to specific **training resources**: <https://go.edqm.eu/Rstraining>
- Dedicated **customer support** through the RS Online FAQs and HelpDesk: <https://go.edqm.eu/HDRs>
- **Online catalogue updated daily**: Prices and product information, including access to batch validity statements (BVSS), safety data sheets (SDSS), leaflets and origin of goods (PDF): <https://go.edqm.eu/crsdb>
- **Catalogue**: <https://go.edqm.eu/RScatalogue>
- **Orders**: <https://store.edqm.eu>

WHO International Standards for Antibiotics (ISAs) and Chemical Reference Substances (ICRSs)

- The EDQM distributes WHO ISAs and WHO ICRSs.

■ **Online databases updated daily**: access to safety data sheets, leaflets, origin of goods and study reports (only for ISAs), available online (PDF).

■ **ISAs**: reference substances for use as **primary standards in microbiological testing of antibiotics**. ISAs can also be used by regional or national pharmacopoeias to establish secondary standards: <https://go.edqm.eu/ISAen>

■ **ICRSs**: primary chemical reference substances, supplied for use in **physical and chemical tests and assays** described in the International Pharmacopoeia or other WHO quality assurance documents: <https://go.edqm.eu/ICRSen>

Monthly EDQM e-Newsletter

■ Regular updates highlighting changes in availability and other information: <https://go.edqm.eu/Newsletter>



CERTIFICATION OF SUITABILITY TO THE MONOGRAPHS OF THE PH. EUR. (CEP)

CEPs: make a difference to your business

- For **active substances or excipients** covered by a **monograph in the Ph. Eur.**, including herbal products and all products with Transmission Spongiform Encephalopathy (TSE) risk.
- CEPs replace data in the **quality part of marketing authorisation applications (MAAs)** and facilitate the management of MAAs.
- **Centralised evaluation** of quality dossiers.
- **Recognised in all 39 Ph. Eur. member states** and beyond.
- Complemented by a **risk-based inspection** programme of manufacturing sites.
- For more information on the certification procedure: <https://go.edqm.eu/CEPbackground>
- For more information on a given substance, CEP holder or the validity of a CEP: <https://go.edqm.eu/CEPdatabase>

■ Access to CEP training resources:
<https://go.edqm.eu/CEPtraining>

■ Access to CEP online FAQs and HelpDesk:
<https://go.edqm.eu/HDceps>



FIND OUT MORE

Events, training sessions, webinars and conferences organised all year round

■ Unique opportunities to **interact directly** with the EDQM, experts and key speakers from around the world to learn more about the European Pharmacopoeia and related subjects: <https://go.edqm.eu/events>

Stay connected with the EDQM

■ Keep in touch with the EDQM and get the latest news on products and services by subscribing to the **e-Newsletter** and following the EDQM on **social media**: <https://go.edqm.eu/StayConnected>

EDQM user support service for any queries

- Includes FAQs and access to the HelpDesk to ask your questions. Please check the FAQ section to see if your question has already been answered.
 - ▶ Publications: <https://go.edqm.eu/HDpubs>
 - ▶ Reference standards: <https://go.edqm.eu/HDrs>
 - ▶ CEPs: <https://go.edqm.eu/HDceps>



ORDERING INFORMATION

All orders are subject to the EDQM's Terms and Conditions of Sales, available here:

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

1. How to order

- ▶ **EDQM Store:** <https://store.edqm.eu>
- ▶ **E-mail:** send the order as an attachment on your company letter-head to orders@edqm.eu

Please ensure your order clearly indicates:

- ▶ **an invoicing address and a full delivery address** (no P.O. Box). EDQM publications ordered by a bookseller are sent to the bookseller's address, not to the end user;
- ▶ **a contact person for invoicing and for delivery**, including their name, telephone number and e-mail address;
- ▶ **the name, catalogue code and quantity** for each item you wish to order.

2. Delivery time and Incoterms

Orders for in-stock reference standards and publications are shipped within **seven working days** (average delay) of order confirmation by the EDQM; otherwise, products are shipped when they become available. Exception: controlled standards – delivery after reception of the import permit and/or export permit.

Orders are shipped either **DAP, CIP or CPT** depending on the **item type**.

3. Prices

Find prices and availability under each product item at:

- ▶ Publications: <https://store.edqm.eu>
- ▶ Ph. Eur. RSs: <https://go.edqm.eu/crsdb>
- ▶ WHO ISA RSs: <https://go.edqm.eu/isadb>
- ▶ WHO ICRSs: <https://go.edqm.eu/icrsdb>
- ▶ CEPs: <https://go.edqm.eu/CEPfees>
- ▶ Events: <https://go.edqm.eu/events> (applicable fees available on each event web page)

Prices are given **exclusive of duties and tax**. Purchasers are responsible for contacting their national fiscal or customs authorities to pay any duties and taxes due.

Booksellers receive a **discount on publications**. No discounts are granted on reference standards.

4. Handling charges

- ▶ **Publications:** €30 per volume (€90 per Ph. Eur. annual subscription). These charges do not apply to orders placed through the **EDQM WebStore**.
- ▶ **Reference standards:** €2.50 per sales unit ordered.

5. Payment terms

- ▶ **Payments can be made by credit card** through the EDQM WebStore (<https://store.edqm.eu>) or by bank transfer.
- ▶ If a credit line has been authorised by the EDQM, payment terms are **30 days end of month**.

Find complete information on:

- ▶ order and dispatch of RSs and publications: <https://go.edqm.eu/PDForder>
- ▶ how to apply for CEPs and prices: <https://go.edqm.eu/CEPapply> and <https://go.edqm.eu/CEPrenew>
- ▶ upcoming events and prices: <https://go.edqm.eu/events>

Contact the EDQM

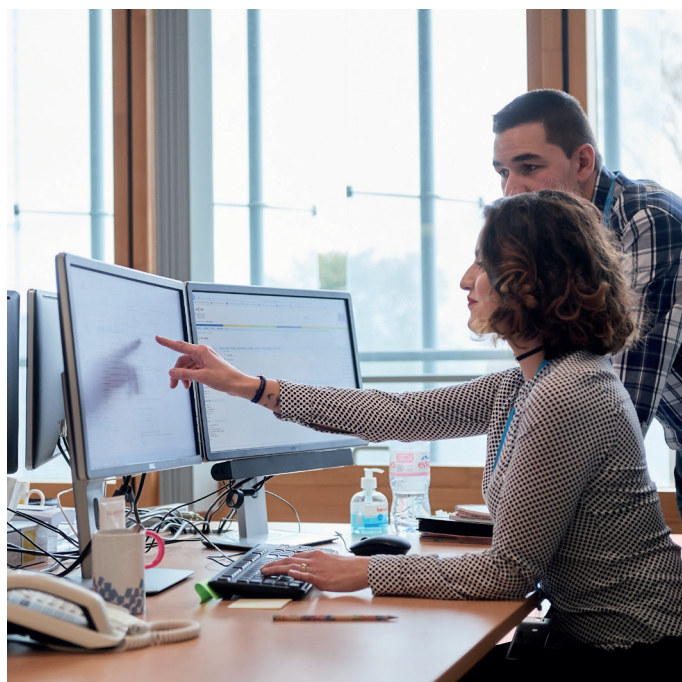
FAQs (all EDQM activities): <https://go.edqm.eu/hdEN>

HelpDesk login: <https://go.edqm.eu/HDlogin>

Telephone: +33 (0)3 88 41 30 30

Postal address:

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F-67000 Strasbourg – France



This catalogue presents an overview of pharmacopoeia related products and services available from the European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe.

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



www.edqm.eu

The Council of Europe is the continent's leading human rights organisation. It comprises 46 member states, including all members of the European Union. All Council of Europe member states have signed up to the European Convention on Human Rights, a treaty designed to protect human rights, democracy and the rule of law. The European Court of Human Rights oversees the implementation of the Convention in the member states.