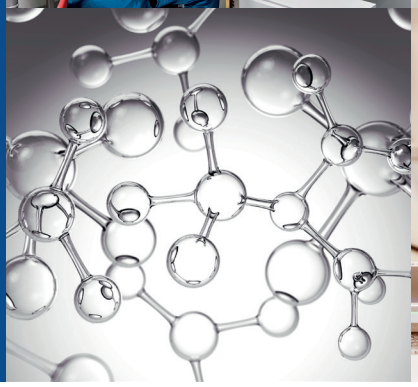
EDQM

Overview of pharmacopoeia related products & services

European Pharmacopoeia

11



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

www.edqm.eu
https://store.edqm.eu

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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

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

- 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

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

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- 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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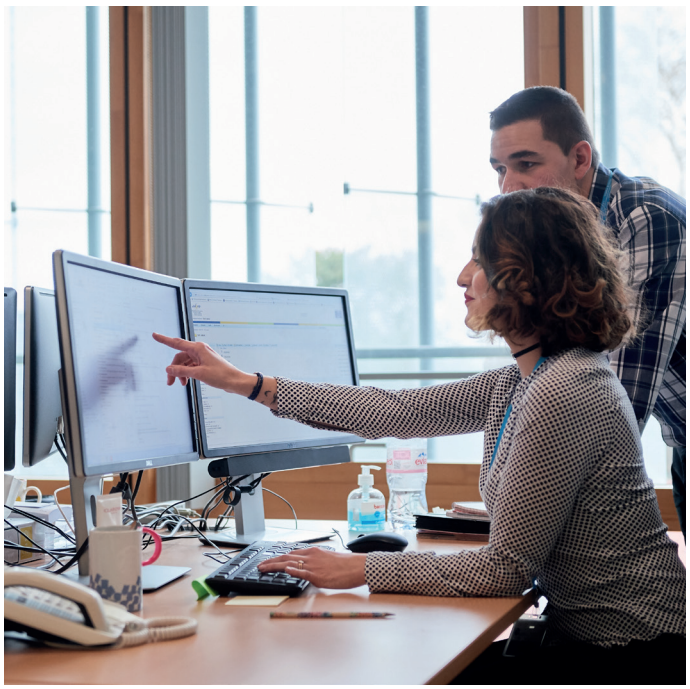
7 allée Kastner, CS 30026
F-67000 Strasbourg – France



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

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