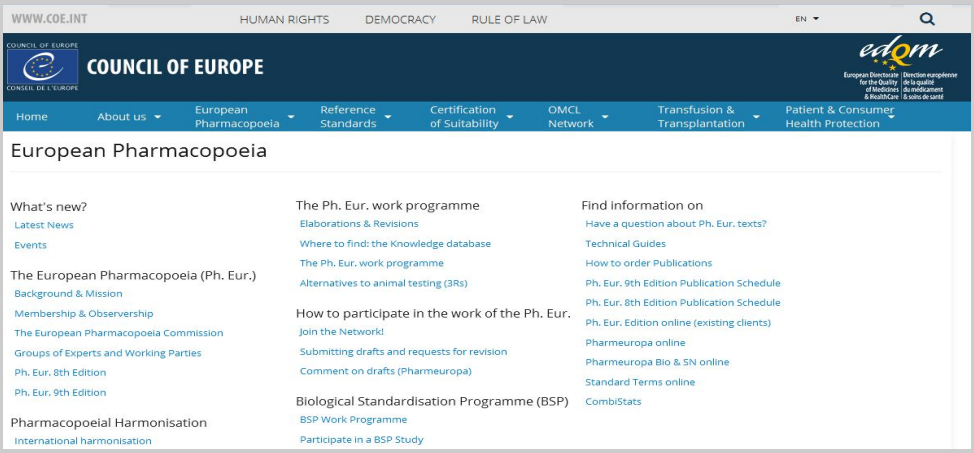
Name of the Tool	European Pharmacopoeia
Home Page	
Logo	
URL	https://www.edqm.eu/
Subject	Pharmacopoeias --Europe; Medicine-- Europe--Standards
Accessibility	On subscription
Language	Bilingual (English, France)
Publisher	European Directorate for the Quality of Medicines & HealthCare (EDQM), a directorate of the Council of Europe.
Brief History	The **European Pharmacopoeia** is a major regional pharmacopoeia which provides common quality standards throughout the pharmaceutical industry in Europe to control the quality of medicines, and the substances used to manufacture them. The 1st Edition of the European Pharmacopoeia was published in 1969, and comprised 120 texts. The 8th Edition, comprising more than 2,500 texts, was published in July 2013, and is currently in force. The 9th Edition, which was published in July 2016 and will come into force on 1 January 2017, contains some 2,300 monographs, and more than 350 general chapters, illustrated with diagrams or chromatograms, and over 2,500 descriptions of reagents. With 121 new and 1,403 revised texts, over 50 percent of the 9th Edition's content is new compared to the 8th Edition. It consists of three initial volumes (9.0), and will culminate in a collection of eight non-

	cumulative supplements (9.1 to 9.8). A new edition is published every three years: in both English and French, by the Council of Europe. It is made available in print and electronic (online and USB stick) versions; the online version is also accessible from smart phones and tablet computers.
Scope and Coverage	European Pharmacopoeia is a published collection of monographs which describe both the individual and general quality standards for ingredients, dosage forms, and methods of analysis for medicines. These standards apply to medicines for both human and veterinary use. The European Pharmacopoeia is a single reference work for the quality control of medicines in the signatory states of the Convention on its elaboration. It is the pharmaceutical industry in Europe.
Kind of Information	The purpose of the European Pharmacopoeia is to promote public health by the provision of recognized common standards for the quality of medicines and their components. Such standards are to be appropriate as a basis for the safe use of medicines by patients. In addition, their existence facilitates the free movement of medicinal products in Europe and beyond. The European Pharmacopoeia is widely used internationally. As globalization and expansion in international trade present a growing need to develop global quality standards for medicines, the Commission works closely with all users of the Pharmacopoeia worldwide. European Pharmacopoeia under the "Reference Standards" heading provides chemical reference substances (CRS) and biological reference preparations (BRP) as well as reference spectra for the tests and assays to be carried out in accordance with the official methods prescribed in the European Pharmacopoeia. The catalogue lists all the reference standards officially valid for the uses prescribed in the European Pharmacopoeia monographs. It is updated daily. To access the most updated information about our reference standards there is an online database which is updated daily and gives access to all our reference standards as well as to a list of newly adopted standards and batches and their released dates (click on New to consult this list), Batch Validity Statement (BVS) for each reference standard, Safety Data Sheets, Leaflets. On 4 May 2006, as decided during the 56th meeting of the WHO Expert Committee on Biological Standardization (ECBS), the EDQM took over responsibility for the establishment, storage and distribution of WHO International Standards for Antibiotics (ISA) from the National Institute for Biological Standards and Control (NIBSC). ISA are generally intended for the establishment of regional or national secondary standards subsequently used in routine laboratory tests and assays.
Special Features	➢ European Pharmacopoeia includes MELCLASS Database on the Classification of Medicines as Regards their Supply. The MELCLASS Database is hosted by the European Directorate for the Quality of Medicines and HealthCare (EDQM) and is supervised by the Committee of Experts on

	the Classification of Medicines as Regards their Supply (CD-P-PH/PHO). ➢ It also includes the MEDICRIME Convention map which indicates the signatures of members and non members' states of Europe and ratifications of the MEDICRIME convention.
Remarks	European Pharmacopoeia monographs and other texts are designed to be appropriate to the needs of regulatory authorities; those engaged in the quality control of medicinal products and their constituents; manufacturers of medicinal products and their individual components. It is used as an official reference to serve public health.
Comparable Tools	➢ International Pharmacopoeia (http://apps.who.int/phint/en/p/about/) ➢ Indian Pharmacopoeia Commission (http://ipc.nic.in/) ➢ Chinese Pharmacopoeia (http://wp.chp.org.cn/en/index.html) ➢ United States Pharmacopeia (http://www.usp.org/) ➢ British Pharmacopoeia (https://www.pharmacopoeia.com/)
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