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European Pharmacopoeia 10th Edition: continuous updates to address new challenges

The newly released 10th Edition of the European Pharmacopoeia, contains 2 420 monographs and 373 general texts (including general monographs and methods of analysis), as well as around 2 780 descriptions of reagents. In total, 114 new monographs have been introduced*¹, of these 17 concern active substances of high medical interest covering key therapeutic classes, such as antineoplastics, immunosuppressants, anti-arrhythmics, anti-thrombotics, antiretrovirals or analgesics; and 7 monographs concern finished products containing chemically defined active substances.

Altogether 683 revisions* were made, taking into account the latest scientific and technical evolutions, legal and regulatory developments, the increasing demand for generic and biosimilar products, new risks in the public health domain and the globalisation of trade and commerce.

Dr Susanne Keitel, EDQM's Director explained that: *'This updated Edition responds to the latest developments in the pharmaceutical sector and defines quality and safety standards for medicines on the basis of scientific expertise. It includes a whole variety of new substances and products, while reflecting the latest scientific and technological advances, as well as recent changes in regulatory processes at European and international level.'*

In the 10th Edition of the European Pharmacopoeia, thoroughly revised general chapters include those on *Infrared absorption spectrophotometry* and on *Ultraviolet and visible Absorption spectrophotometry*, with the latter now covering UV-Vis detectors for chromatographic systems and for Process Analytical Technology applications. Acceptance criteria for elemental impurity levels, as defined in the ICH Q3D guideline, are also reflected in this new edition, which also provides standardised approaches for correctly determining elemental impurity levels. Further work on elemental impurities included the revision of the general monographs on *Substances for pharmaceutical use* and *Pharmaceutical preparations*, the general chapters on *Elemental Impurities and their Determination*, as well as numerous individual monographs.

In the field of biologicals, several new monographs address both existing and innovative treatments, such as *Infliximab concentrated solution (2928)*, the revised general monograph on *Products of recombinant DNA technology* and a new chapter on the *Quantification and characterisation of residual host cell DNA*. All offer quality standards for a wide range of biological medicines while allowing for the necessary flexibility.

The 3Rs concept (replacement, reduction and refinement), which is aimed at protecting animals used for scientific purposes, is widely reflected in the 10th Edition. The *test for abnormal toxicity* was completely removed, and altogether, 49 individual monographs, 36 of which concern vaccines for human use, were revised. Another step is the new chapter on the *Substitution of in vivo methods by in vitro methods for the quality control of vaccines*, which will ease the transition from in vivo to in vitro methods. In total 59 monographs were revised in this context.

The 10th Edition of the European Pharmacopoeia will become effective as of 1st January 2020 and will be updated with 8 supplements over the following 3 years (10.0 to 10.8). Functionalities of the electronic versions have been improved to better address users' needs. This allows more effective user management, including re-allocation of access rights amongst your users. More information on the 10th Edition [here](#).

¹ *Compared to Edition 9.0



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Note for the Editor: Further information is available on the internet site <https://www.edqm.eu/>

The EDQM is a leading organisation that protects public health by enabling development, supporting implementation, and monitoring the application of quality standards for safe medicines and their safe use. Our standards are recognised as a scientific benchmark worldwide. The European Pharmacopoeia is legally binding in member states². Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

²There are thirty-nine members of the [European Pharmacopoeia](#) Commission: *Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Republic of Moldova, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, The Republic of North Macedonia, Turkey, Ukraine, United Kingdom and the European Union.*

A political organisation set up in 1949, the Council of Europe works to promote democracy and human rights continent-wide. It also develops common responses to social, cultural and legal challenges in its 47 member states.