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EDQM rolls out reference standards for elemental impurities: lead, cadmium, mercury and arsenic

The European Directorate for the Quality of Medicines and Healthcare (EDQM) announces the availability of four new elemental impurity chemical reference standards (CRS) in its [European Pharmacopoeia catalogue](#): lead solution CRS, cadmium solution CRS, mercury solution CRS and arsenic solution CRS. These elements occurring in nature are amongst the greatest potential sources of elemental contamination in medicinal products and substances for pharmaceutical use; the new reference standards underpin the European Pharmacopoeia (Ph.Eur.) chapter describing the determination of elemental impurities (2.4.20).

Element contents featured in these reference standards – which were developed in partnership by EDQM, the Joint Research Centre (JRC) of the EU Commission, the National Metrology Institute of Germany, Physikalisch-Technische Bundesanstalt (PTB), and the German Federal Institute for Materials Research and Testing (BAM) - are traceable to the SI (International System of units of measurements) and enable metrologically sound determination of lead, cadmium, mercury and arsenic as elemental impurities in medicinal products and substances for pharmaceutical use.

With the introduction of these reference standards, the EDQM is providing a tool that can support pharmaceutical manufacturers in their implementation of relevant public health standards, such as the ICH Q3D on Elemental Impurities, the quality guideline for the control of impurities in medicinal products.

For more information visit the [EDQM website](#).

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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 states¹. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

¹There 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 former Yugoslav Republic of 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.