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Joint EDQM-USP symposium illustrates use of pharmacopoeial reference standards

Established specifically for their intended use, pharmacopoeial reference standards are thoroughly characterised and their uses may go beyond those described in compendia, although a clear-cut distinction between quantitative use and qualitative use is essential. For example, compendial assay standards for APIs may be used for assay of finished products as long as specific criteria are fulfilled, as stated in chapter 5.12 of the European Pharmacopoeia (Ph. Eur.).

This clarification came during the "13th International Symposium on Pharmaceutical Reference Standards (IRSS)" organised in Strasbourg on 13-14 March by the EDQM and the United States Pharmacopeia (USP), which included dedicated sessions focusing on pharmacopoeial reference standards and their use and establishment, covering reference standards for biologicals and small molecules.

The EDQM and USP explained that pharmacopoeial reference standards underpin compendial analytical procedures and specification limits and are essential for compliance with regulatory requirements in the respective region. As pharmacopoeial reference standards are extensively characterised with state-of-the-art technology, their use should be preferred whenever an official source exists.

With biological medicines, biological reference standards play a pivotal role in ensuring standardisation of measurement results. However, while reference standards such as infliximab CRS and infliximab BRP are qualified for the intended use of determining pharmaceutical quality according to standards, they are not to be used in contexts other than quality control, such as in *in vivo* assays or for demonstrating biosimilarity. The clarification came as participants in the symposium remarked that, in spite of the growing importance of biological medicines, measurement issues seem to persist due to the inherently variable nature of these medicines.

Pharmaceutical reference standards for small molecules were also broadly discussed during the symposium, with a focus on advanced scientific approaches for their characterisation, and users' needs and expectations. It was highlighted that a number of new Ph. Eur. reference standards for equipment or method performance control had been introduced in recent years. This is the case of reference standards for elemental impurities, which are needed to ensure compliance with compendial specifications recently introduced via ICH Q3D.

More information on the EDQM reference standards and on how to participate in establishment studies can be found here: https://www.edqm.eu/en/ph-eur-reference-standards-purpose-and-use

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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 states[1]. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

[1]There 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.

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