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Revised General Chapter on Raman Spectroscopy in the European Pharmacopoeia: inclusion of handheld devices, adaption to PAT purposes

Corresponding Reflection paper on the rationale published

The European Pharmacopoeia Commission has revised its General Chapter on Raman Spectroscopy (2.2.48). The revised chapter is published in Supplement 8.7 and enters into force on 1 April 2016. The chapter has been completely rewritten and has been given a new structure.

The General Chapter 2.2.48 was first presented in the 4th edition of the European Pharmacopoeia in 2002. Since then Raman Spectroscopy has received more and more attention in pharmaceutical applications. It is nowadays used regularly for the identification and characterisation of material in the laboratory environment. Newer Raman technologies have become available and existing ones have been developed further. Hand-held instruments are now available on the market, which are suitable for identification purposes even though requiring different tolerances for the wavenumber scale verification than benchtop models.

In addition, Raman spectroscopy is increasingly used for Process Analytical Technology (PAT) or for chemical imaging applications. One focus of the revision was therefore to ensure full applicability of the chapter to the potential use of this technique in a PAT environment.

This general revision covers an update of the reference standards or reagents used for verification of the wavenumber scale. From the previous selection cyclohexane has been kept while indene and naphthalene have been replaced by polystyrene and paracetamol. Polystyrene standards are widely available and already used in practice. Paracetamol is a very relevant substance for the pharmaceutical industry: stable and easy to work with. The European Directorate for the Quality of Medicines and HealthCare (EDQM) now provides a defined Chemical Reference Substance "paracetamol for equipment qualification CRS". With these three reference standards and reagents, liquid, powder and polymer materials are covered. This enables the user to choose a standard typical of the physical state of the material to be examined.

For selection of appropriate wavenumber shifts and tolerances, an inter-laboratory study was organised. Tolerances were fixed for benchtop instruments including dispersive, Fourier transform and microscope instruments and for hand-held instruments. Details on the study and selection of the tolerances can be found in a corresponding reflection paper published in [Pharmeuropa Bio & Scientific Notes 2015](#) Rationale for the Update of the European Pharmacopoeia General Chapter 2.2.48 Raman Spectroscopy.

The European Pharmacopoeia is also elaborating a chapter on Chemical Imaging which will be open for public consultation from April till June 2016. Please refer to our free online journal [Pharmeuropa](#) at that time.

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Note for the Editor: Further information is available on the internet site 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 world-wide. 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-eight 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, 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.*

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