



**05 April 2018, Strasbourg, France**

## **The Ph. Eur. revises its general chapter on Infrared Absorption Spectrophotometry**

At its 160<sup>th</sup> session (March 2018) the Ph. Eur. Commission adopted a new version of one of its major general methods, which has undergone extensive revision. The chapter on *Infrared Absorption Spectrophotometry (2.2.24)* is one of the original cornerstones of pharmacopoeial testing, referenced in many general texts and more than 1200 individual monographs.

The chapter has been completely rewritten and its structure updated to include:

- the removal of monochromator instruments as they are now obsolete;
- an extended description of Fourier-transform spectrometers (FT-IR) using attenuated total reflection (ATR) and related criteria for the control of equipment performance;
- a new "principle" section, with distinction between near-, mid- and far-infrared;
- new sections on applications and limitations;
- a reduction from 7 to 4 band positions for verification of the wavenumber scale following the removal of monochromator instruments, and addition of slightly shifted band positions for ATR FT-IR instruments;
- guidance on the use of stored spectra and internal libraries;
- a description of procedures for the comparison of spectra.

It is highlighted that the new band positions – and the associated acceptable tolerances – proposed for the verification of the wavenumber scale have been established based on experimental data gathered during two series of round-robin tests by different laboratories using different instruments.

Four suitable band positions were included in the testing to cover a large range of wavenumbers and different vibrations (906 cm<sup>-1</sup>, 1028 cm<sup>-1</sup>, 1601 cm<sup>-1</sup> and 3060 cm<sup>-1</sup>). These target wavenumbers were included as they are certified band positions in current reference materials. They also correspond to the following vibrational modes:

- carbon-hydrogen stretching (3060 cm<sup>-1</sup>)
- carbon-carbon stretching (1601 cm<sup>-1</sup>)
- carbon-hydrogen deformation in-plane (1028 cm<sup>-1</sup>)
- carbon-hydrogen deformation out of plane (906 cm<sup>-1</sup>)

The spectral range for verification is now broader – a value below 1000 cm<sup>-1</sup> is now included – and extended toward the region that is most useful for identity testing.

A broad panel of instruments was used for the study and the results obtained show that there is always a band shift towards lower wavenumbers when using ATR FT-IR instruments. It was then decided to focus on fixing appropriate target values for ATR instruments, rather than expanding tolerances. Different wavenumbers, but the same acceptable tolerance (+/- 1 cm<sup>-1</sup>), are thus given for FT transmission and FT ATR instruments in the revised chapter.

The revised chapter on *Infrared Absorption Spectrophotometry (2.2.24)* will be published in Ph. Eur. Supplement 9.7 and will become effective in April 2019.

**Contact:** Caroline Larsen Le Tarnec, Public Relations Division, EDQM, Council of Europe



Tel.: +33 (0) 3 88 41 28 15 - E-mail: [caroline.letarnec@edqm.eu](mailto:caroline.letarnec@edqm.eu)

**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<sup>1</sup>. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

<sup>1</sup>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 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.*