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NEW GENERAL CHAPTER ON CHEMICAL IMAGING IN THE EUROPEAN PHARMACOPOEIA

The chapter on Chemical Imaging (5.24) was adopted by the European Pharmacopoeia Commission at the end of November 2016. The Vibrational Spectroscopy and Analytical Data Modelling working party (VSADM) has produced the first such chapter to be included in any pharmacopoeia worldwide.

This general chapter is intended to further the use of Chemical Imaging (CI) for analysing pharmaceutical products in formulation and analytical development, quality control and manufacturing environments.

Chemical imaging combines sensing technology with data analysis techniques to characterise a sample area in chemical and physical terms. It can be applied to assess the identity, concentration and distribution of pharmaceutical ingredients in bulk or solid dosage forms, biological samples or packaging materials. The chapter focusses on the techniques most commonly used i.e. mid-infrared, near-infrared and Raman spectroscopy. However, it also applies to other techniques that provide images. Chemical imaging enables the user to create visual images of component distribution measured e.g. by vibrational spectroscopy.

Depending on the analytical technique used it is possible for example to detect polymorphism, particle morphology, sample homogeneity, physical sample defects or foreign particles and contaminants.

This non-mandatory chapter of the European Pharmacopoeia offers specific recommendations to assess the performance of chemical imaging systems for qualitative and quantitative investigations. This includes both spectral and spatial components. Where chemical imaging systems are intended for investigative purposes, the performance requirements of other general chapters may not need to be applied.

The text contains amongst others the following elements:

- an introduction to chemical imaging including explanations of datacubes and higher dimensional CI;
- applications;
- a description of selected chemical imaging systems;
- explanations of elements of a chemical imaging process;
- recommendations for control of instrument performance and
- for image processing and image analysis.

The final text will be published in Supplement 9.3 in July 2017.



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

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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.

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