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Determination of Crystallinity by Microcalorimetry and Solution Calorimetry as Standard Tests in Pharmacopoeia

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Crystallinity is an important parameter for the characterization of the solid state of drug candidates, which requires suitable analytical methods. Typical analytical techniques to assess crystallinity as X-ray Powder Diffraction, Thermal Analysis or Optical Microscopy are described in Pharmacopoeia monographs in USP, JP or EP. In the last years calorimetric techniques as microcalorimetry or solution calorimetry were widely employed to assess changes in crystallinity of pharmaceutical powders or to determine the amorphous content. The USP has added a monograph on Determining Crystallinity by Solution Calorimetry (USP <941>). Also Microcalorimetry is used in quality control to monitor small amorphous contents in pharmaceutical powders. It was now proposed to implement a also method on Characterisation of Crystalline and Amorphous Solids by Calorimetric Techniques to European Pharmacopoeia. The presentation gives an overview of some relevant aspects of these techniques in relation to their use in control of pharmaceutical powders.

Reference:

USP <914> Determining Crystallinity by Solution Calorimetry