Solid State Characterization of Active Pharmaceutical Ingredients

Javier Ellena

Depto. de Física e Informática, Instituto de Física de São Carlos, Universidade de São Paulo

The active pharmaceutical ingredients, also known as drugs, are any substance or mixture of substances with biological activity that can be used in the manufacture of a medicament, being its responsible for pharmacological activity. They are mostly administered in solid dosage form (tablet, capsule etc.). However, their therapeutic efficacy is directly related to the characteristics of the solid form of the drug. The crystal structure (three-dimensional internal arrangement of the molecules that comprise a crystal) as well as the crystal habit (external morphology) and the particle size have a major practical and commercial impact, since the initial research steps until the commercialization of the final product. Among the more important physicochemical properties it could mention the dissolution rate and the solubility, the bioavailability and the bioequivalence, the hygroscopicity, the physical and chemical stability and the manufacturability. Therefore, knowledge and control of the formation of crystal modifications are key steps for the pharmaceutical industry. In the same way, the technical characteristics and pharmacological properties of a bioactive molecule may be enhanced through the selection and preparation of certain crystalline modification. That pathway is an attractive alternative to improved pharmaceutical profiles through the use of the solid state supramolecular chemistry. These and other aspects of the influence on the crystalline structure on the quality and physico-chemical properties of a solid pharmaceutical compound will be discussed in a multidisciplinary approach.