CRYSFORMA characterizes polymorphs for the pharmaceutical industry at the ALBA Synchrotron

CRYSFORMA, a unit from the Institute of Chemical Research of Catalonia (ICIQ) managed by Dr. Jordi Cerón, provides complete scientific support to the pharmaceutical and fine chemistry industry in the field of pharmaceutical solid state development. CRYSFORMA is currently applying its expertise to use the ALBA synchrotron facilities in its projects in the area of polymorphism.

Polymorphism is the ability of a solid substance to crystallize in more than one crystalline structure, resulting from a different arrangement of the molecules within the crystal lattice. Each of these different crystalline phases are known as polymorphs. Polymorphs of Active Pharmaceutical Ingredients (APIs), although being the same chemical entity, can have different physicochemical properties, which can affect the bioavailability of the final drug, or its processability during the manufacturing process. For this reason polymorphs are of special interest in the pharmaceutical industry.

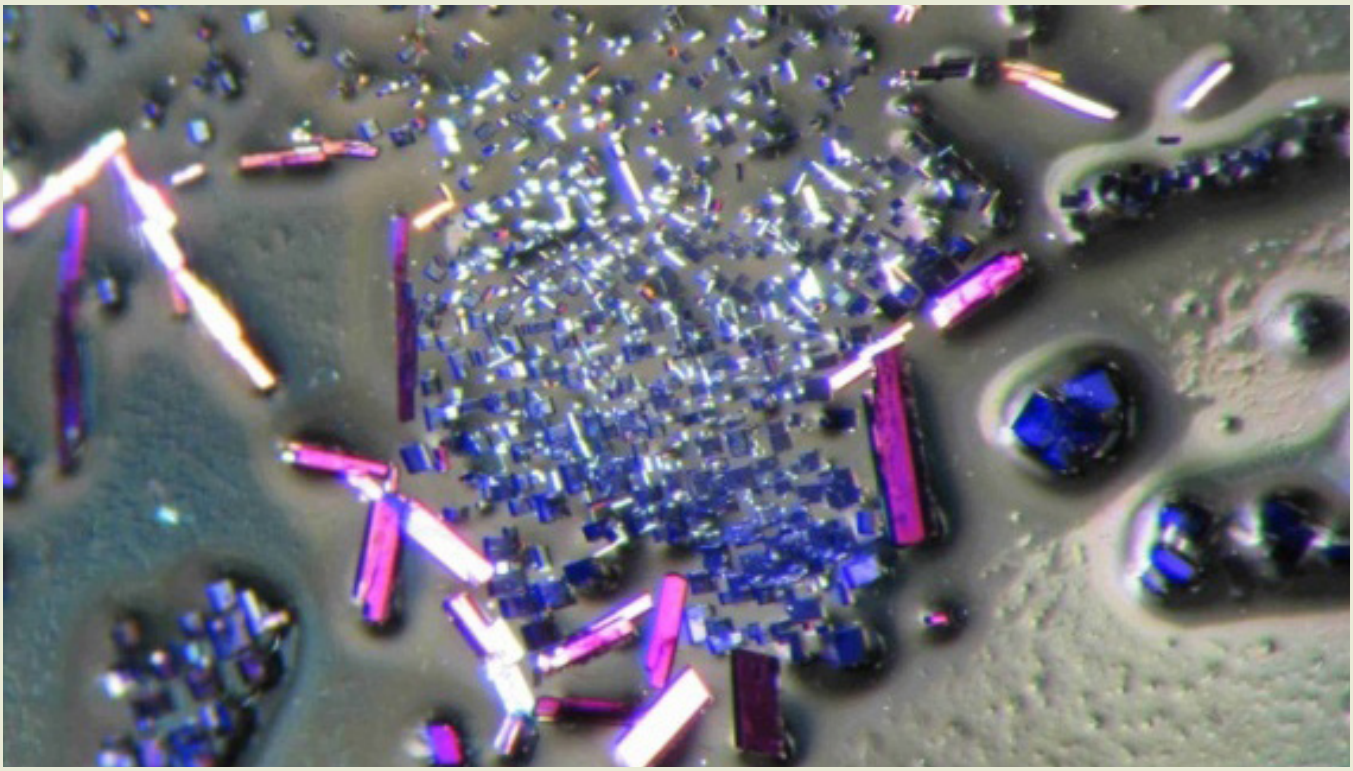
Powder X-ray diffraction (PXRD) is probably the most extended analytical technique in development and analytical laboratories to determine the polymorph present in an API or drug sample and to ensure the absence of undesired polymorphs. Although a standard laboratory PXRD diffractometer is a fairly powerful technique with a detection limit acceptably low (0.1-1% depending on the API), sometimes even lower quantities of an undesired polymorph need to be detected in order to avoid transformation (due to microseeding), to comply with regulatory aspects or to avoid any legal issues concerning patent infringement.

These technical principles can be applied using the high energy synchrotron light at ALBA (beamline BL04 - MSPD: Materials Science and Powder Diffraction), giving more sensitive data and a much better peak resolution. Thus, the signal intensity compared to the background noise is increased, and the broadness of signals is reduced, which allows lowering the detection limit in a much shorter time of analysis.

CRYSFORMA is currently using the ALBA synchrotron facilities to solve different issues concerning the characterization of the solid state of APIs, offering the service of analysis and data interpretation to the pharmaceutical industry.

Further information:
www.iciq.com
www.crysforma.com

CRYSFORMA
crystallization solutions



Microphotography of crystals with different morphology corresponding to different polymorphs. Image courtesy of CRYSFORMA.