



CRYSFORMA

PXRD ANALYSIS

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POWDER X-RAY DIFFRACTION SERVICES

Polymorph quantification and detection limit determination

Development of analytical methods for the quantification of a given polymorph in a mixture and the determination of the limit of detection (LOD). Crysforma has developed a measurement procedure to be able to quantify a given polymorph and determine its presence with very low detection limits (typically in the range of 0.3 and 1%, depending on the API). The same procedure can be applied in mixtures of different crystalline products (API 1 + API 2, API + excipient, etc).

Fast analysis service

Crysforma offers a fast and reliable powder X-Ray diffraction service, including several analysis types:

- ▶ Crystalline phase identification, comparing against standards defined by the company.
- ▶ Measurements according to specific analytical methods developed by Crysforma.
- ▶ Component search in specialized databases.

Variable temperature PXRD

On its own or in combination with other thermal analysis techniques, VT-PXRD can provide useful information regarding crystal structure, dehydration / desolvation, phase transitions, melting and decomposition of pharmaceutical compounds.

PXRD analysis at the synchrotron

Sometimes the standard and most available analytical instruments are not enough to get the needed intensity and sensitivity required to solve specific analytical problems and more powerful instrumentation is necessary to obtain the answers.

The radiation based in the synchrotrons is amongst the most powerful in instrumental analysis and is becoming fundamental in many industrial applications, particularly in the characterization of the solid state of APIs and final drug products. This radiation can be applied in a broad range of X-ray techniques improving the signal intensity, sensitivity and definition.

CRYSFORMA is now offering analysis using the ALBA synchrotron facilities to bring this high technology closer to the industry to solve the problems that cannot be solved in conventional equipment.

The intensity, resolution and signal definition obtained in the analysis performed using the high energy radiation of a synchrotron makes it of special interest in the following issues:

- ▶ Differentiation of two very similar polymorphs of an API.
- ▶ Lowering the limit of detection of a polymorph of an API or drug product.
- ▶ Detection and quantification of determined polymorphs in complex mixtures, for example of a formulated drug product.
- ▶ Structure elucidation based on powder X-ray diffraction.





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SOLUBILITY STUDIES

Solubility screening

Solubility screening studies provide information on the best solvent media for a given crystallization process. Solubility data is also relevant during pre-formulation evaluations of APIs. Solubility curves and metastable zone width in a given solvent are determined with small amount of API and in a short period of time.

Intrinsic dissolution

An additional characterization of bulk drug substances and excipients is the measurement of intrinsic dissolution rates. Its determination can be in some cases important since bioavailability of an API is influenced by the dissolution rate. Furthermore, intrinsic dissolution tests are a way to prove chemical purity, batch-to-batch consistency and sameness after changes in production.

OTHER SERVICES

Amorphous content

Mechanical stresses during processing may introduce small amounts of amorphous material which can have a relevant effect on the products properties, including solubility and stability. Crysforma applies several available analytical techniques (PXRD, thermal analysis, GVS) to determine small amounts of amorphous phase in a crystalline solid.

Solid form hygroscopicity and stability

Use of gravimetric vapour sorption (GVS) and climatic chambers to determine the effects of relative humidity and temperature on the solid form of interest.

