CRYSFORMA

POLYMORPHISM & CRYSTALLIZATION

CRYSFORMA offers complete scientific support to discover and characterize the most relevant polymorphs of a drug and to select the candidate with optimal solid state properties.

Polymorphism, the ability of a chemical compound to crystallize in more than one crystalline phase, is a key issue in the pharmaceutical industry. Different polymorphs can have different physical and chemical properties, and thus can have an influence on the bioavailability of the pharmaceutical compound. Additionally, polymorphism is key to patent strategy, as different polymorphs can give rise to independent IP claims.

Moreover, the relative stabilities of the different polymorphs must be known in order to avoid unwanted polymorph transformations during production of the active pharmaceutical ingredient or in the final pharmaceutical compound.

TYPE OF STUDIES

- Initial or fast polymorphism screening for early stage candidates.
- Comprehensive polymorphism study of a drug substance.
- Determination of the relative stability of the different polymorphic forms.
- Scale-up of the selected polymorphs.
- Development of analytical methods for polymorph quantification.
- Crystallization of compounds that are difficult to crystallize or that are formerly known only as amorphous solids.
- Crystallizations oriented to the generation of single crystals for single crystal X-ray diffraction structure determination.

METHODOLOGY

The unit has developed its own crystallization screening methodology based in the use of several crystallization procedures, oriented to obtain the thermodynamically stable phase as well as kinetically favoured phases. Moreover, solvent-mediated as well as solvent-free crystallization procedures are assayed. We use small scale high throughput crystallization systems controlled by highly skilled scientists to maximize the information drawn from each experiment.

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