CASE STUDY

Understanding the Polymorph Landscape of an API

The challenge

A thorough understanding of polymorphism is a key requirement for the regulatory approval of a new drug. Our customer's API was challenging; prior knowledge was fragmented, the API was poorly crystalline and there were limited solvent options due to solubility challenges, gelling, and solvation.

How?

The CatSci team repeated previous work and thoroughly characterised the known forms. An augmented polymorph screen was performed employing slurrying, evaporation, and recrystallisation methods. All screen hits were characterised using XPRD, DSC, TGA, and microscopy techniques.

The achievement

Through CatSci's successful polymorph screening:

- 19 discrete XRPD patterns were identified, including many solvates.
- A diagram was constructed showing how all forms interrelated.
- A crystalline mono-hydrate was identified as a development candidate.
- The knowledge gained was sufficiently thorough for future regulatory scrutiny.

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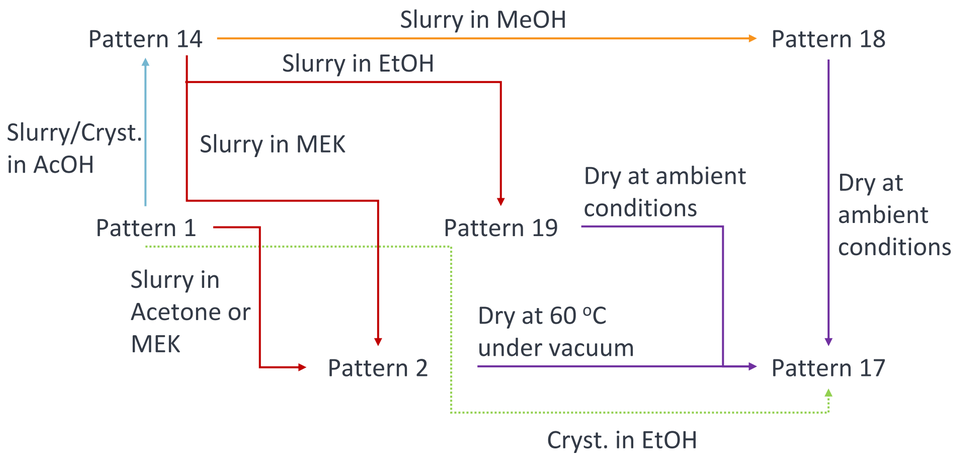
Polymorph Interrelationship



Blaze metrics image taken during a Mono-hydrate crystallisation