Poster Presentation

Development of pharmaceutically acceptable crystalline forms of APIs

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Polymorph screening of API often results in pesudpolyomorphs (solvates) which are pharmaceutically unacceptable. However in some cases, these solvates can be transformed to acceptable hydrates via exchange of the lattice solvent in the solid state. Developing a robust process for such solid-state transformations requires in-depth understanding of molecular–level phenomena, critical process parameters and appropriate technologies for scale-up. This poster describes, two API's where alcohol solvates were converted to hydrates. Interestingly, these hydrates could not be directly crystallized from water but could be obtained only through solid-state solvent exchange of the solvates by humidification. Design of Experiments was conducted to identify critical process parameters during humidification and crystallization that impacted the kinetics and effectiveness of solvent exchange. Mechanistic insight of the phenomena was gained through single crystal structure elucidation and molecular modeling.

Internal commnication No: IPDO IPM-00531

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Keywords: API, Solid-state transformations, Solvent exchange