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ISO-STRUCTURALITY INDUCED SOLID PHASE TRANSFORMATIONS: A CASE STUDY WITH LENALIDOMIDE

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Comprehensive study for the isolation/characterization on pharmaceutical solids like polymorphs, salts, hydrates, solvates, co-crystals etc. are integral part of pharmaceutical industry. Further the selected solid form should meet the basic requirements of optimal stability, reproducibility and scalability which will eventually lead to devise a robust and reliable process for its manufacture. The existence of more than one crystal structure for a chemical substance is referred as polymorphism. Polymorphs of active pharmaceutical ingredients (API's) have always drawn attention in view of their physical and intellectual property. The importance of polymorph screening can be visualized by a fact of sudden appearance or disappearance of a polymorphic form during manufacturing and storage. These transformations will lead to a series of serious consequences in terms of, patient safety, finance and brand value of the company and so on. The probability of getting polymorphs of an API depends on the conformational flexibility existing in the molecular structure and diversity in the crystal packing. The main objective of the current work was to discover novel polymorphs of LDM and investigate the existence of iso-structurality in them. Thorough investigations were carried out to find the relationship of iso-structurality with de-hydration and de-solvation behavior. In the process of polymorph screening various novel forms along with the reported forms of LDM were isolated and analyzed by various analytical techniques. In the current paper, we have selectively focused on polymorphism, iso-structurality and mechanism of de-solvation/de-hydration in pseudo polymorphs of Lenalidomide.

BIOGRAPHY

R Ravichandra Babu has completed his PhD from Andhra University, Visakhapatnam, India. He is the Director/Professor of Gitam University, India. He had several years of experience in the QA and QC departments of a chemical industry, where he has developed many analytical methods for process related impurities determination. He has over 40 publications and has been serving as an editorial board member of reputed journals.

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