

Polymorphism In The Pharmaceutical Industry

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Polymorphism In The Pharmaceutical Industry

1 . ANDAs: Pharmaceutical Solid Polymorphism Chemistry, Manufacturing, and Controls Information . This guidance, represents the Food and Drug Administration's (FDA's) current thinking on this topic.

ANDAs: Pharmaceutical Solid Polymorphism

pharmaceutical industry experience, including work in solid state chemistry, analytical chemistry, stability, pharmaceuticals, regulatory CMC, patents, and litigation. He may be reached at 847.738.0856 and at consultjb@comcast.net. ... Polymorphism may impact product development, clinical studies, product manufacturing, product quality, and ...

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Polymorphism—A Critical Consideration in Pharmaceutical Development ...

The concept of “crystal engineering” was first proposed by Schmidt in 1971. Today, crystal engineering is a powerful tool for designing pharmaceutical solids with desirable physicochemical properties .The diverse structures in pharmaceutical solids, as highlighted by Cherukuvada and Nangia , provide considerable maneuverability for optimizing product quality.

Recent Developments in the Crystallization Process ... - ScienceDirect

92. Pharmaceutical Experimental Design, Gareth A. Lewis, Didier Mathieu, and Roger Phan-Tan-Luu
93. Preparing for FDA Pre-Approval Inspections, edited by Martin D. Hynes III
94. Pharmaceutical Excipients: Characterization by IR, Raman, and NMR Spectroscopy, David E. Bugay and W. Paul Findlay
95. Polymorphism in Pharmaceutical Solids, edited by ...

Pharmaceutical Process Scale-Up

Pharmaceutical solid polymorphism, for example, has received much attention recently since it can impact solubility, dissolution, stability, and manufacturability. Chemical properties include pKa, chemical stability in solid state and in solution, as well as photolytic and oxidative stability. ... Level 3 is the level of control traditionally ...

Understanding Pharmaceutical Quality by Design - PMC

CDER GFI: ANDAs: Pharmaceutical Solid Polymorphism: Chemistry, Manufacturing, and Controls Information Analytical Controls Guidances CVM GFI #63 (VICH GL1) Validation of Analytical Procedures ...

Chemistry Manufacturing and Controls (CMC) Guidances for Industry (GFIs ...

Chemists and engineers in the pharmaceutical industry generally seek to deliver crystalline forms

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of their active compounds, mainly due to the inherent stability of crystalline materials and the well-established impact of crystallization processes on purification and isolation of chemical substances[.].Increasing attention is now being paid to the impact of material properties on drug discovery ...

Co-Crystals: A Novel Approach to Modify Physicochemical Properties of ...

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Alhalaweh A, George S, Basavoju S, Childs SL, Rizvi SAA, Velaga SP. Pharmaceutical cocrystals of nitrofurantoin: screening, characterization and crystal structure analysis. CrystEngComm 2012;14:5078-88. Karki S, Friscic T, Jones W, Motherwell WDS. Screening for pharmaceutical cocrystal hydrates via neat and liquid-assisted grinding.

Pharmaceutical Cocrystals: An Overview

Polymorphism may also include solvation or hydration products (also known as pseudopolymorphs) and amorphous forms. Differences in these forms could, in some cases, affect the quality or performance of the new drug products.

SPECIFICATIONS FOR NEW DRUG SUBSTANCES AND NEW DRUG PRODUCTS (QUALITY ...

Novartis v. Union of India & Others is a landmark decision by a two-judge bench of the Indian Supreme Court on the issue of whether Novartis could patent Gleevec in India, and was the culmination of a seven-year-long litigation fought by Novartis. The Supreme Court upheld the Indian patent office's rejection of the patent application. The patent application at the centre of the case was filed ...

Novartis v. Union of India & Others - Wikipedia

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