Peter H Karpinski, Pharm Anal Acta 2015, 6:1
http://dx.doi.org/10.4172/2153-2435.S1.023

OMICS International
Pharmaceuticalconferences.com

5th International Conference and Exhibition on

Pharmaceutics & Novel Drug Delivery Systems

March 16-18, 2015 Crowne Plaza, Dubai, UAE

Peter H Karpinski

Novartis Pharmaceuticals Corp., USA

Perplex polymorphic behavior of active pharmaceutical ingredients

Different polymorphs of the same drug substance display distinct physical properties, such as melting point, solubility, dissolution rate, hygroscopicity, stability, etc. The ability to successfully produce and reproduce specific stable polymorphs is intricately correlated with the efficiency and speed of drug development, the robustness of manufacturing process, and – ultimately – the stability and quality of active pharmaceutical ingredients (APIs).

This paper focuses on several interesting – and sometimes perplex – case study examples of polymorphs 'behaving badly'. Statistically, 85% APIs exhibit (pseudo)polymorphism, and 50% of APIs have multiple (pseudo)polymorphs. The capability to effectively and consistently manufacture specific stable (pseudo)polymorphs is an integral part of the full API development process. This cannot be accomplished without a thorough and systematic process involving the polymorph discovery stage, polymorph detection, and analytical determination of the properties of the forms discovered. These nontrivial tasks are full of surprises - as in the world of polymorphs confusing results are standard.

Challenging and/or unusual situations are common, such as: occurrence of forms difficult to discriminate amongst, forms difficult to detect, 'disappearing' polymorphs, isostructural forms of same and different molecules, same form but inconsistent properties for different batches, or a new, more stable form is discovered (too) late…

In order to avoid late-stage development surprises, only thermodynamically most stable API forms should be developed. Frequently, such forms are discovered after a significant research and development effort. Multiple complementary techniques must be used in polymorph detection and characterization which, however, is a time-consuming and highlylabor-intensive exercise.

Biography

Peter Karpinski, recently retired from Novartis Pharmaceuticals, USA, is a consultant, expert witness, and trainer in the areas of polymorphism, form/salt selection, and characterization of APIs; and crystallization & precipitation processes. At Novartis, Karpinski was the leader of Particle Engineering and Salt & Polymorphism networks. Karpinski has over 40 years of international experience in research on crystallization and precipitation processes. He taught chemical engineering at Polish and US universities, published several textbooks and over 50 refereed papers, presented dozens of invited papers at national and international symposia, and holds a number of patents.

peterhkarpinski@gmail.com