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A rational approach to polymorph screening based on risk assessment: Regulatory guidelines versus extent of experimental work

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Polymorphic forms have different physicochemical properties that might have significant impact on the intended use of the material - and according to regulatory guidelines a “polymorph screening” should be performed to ensure control of the pharmaceutical compound. However, nothing is stated about the extent of the screening - and as only imagination sets the limits for possible experimental procedures, this screening can be quite time-consuming and expensive. Thus, in many cases such a screening is postponed until later development in order to avoid unnecessary expenses.

A case study is presented where 5 of 6 reported polymorphic forms were found using a very basic experimental setup. The experimental conditions were chosen in order to increase the possibilities of different crystal formations. It is demonstrated that a quite simple set-up might be sufficient in order to find the more “probable” crystal formations - and performing such a basic polymorph screening in very early development highly reduces the risk for failure in later development.

Biography

Karin Liltorp is a Principal Scientist at Particle Analytical ApS, a company performing physical chemical characterization of pharmaceuticals. She got her education from Roskilde University with a Ph.D. in physical chemistry. She has previously been working as Pre-formulation Scientist at Lundbeck.

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