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The “Form Selection Process” in the Pharmaceutical Industry: the importance of being Earnest

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Active Pharmaceutical Ingredients (API) shows the tendency to get order and crystallize as solids in different structures (forms). This phenomenon is known as polymorphism.

In general, different polymorphs show different physicochemical characteristics and properties. Therefore, the selection of the API form for drug product (DP) development is more than critical because the API form itself has a great impact on the properties of the final DP: the form selection problem has ethic, therapeutics, commercial and economic implications.

A number of historical and real industrial examples are presented in order to show how the X-Rays Powder Diffraction (XRPD) is an essential technique for the determination and quantification of polymorphic (or pseudo-polymorphic) forms in a given API to effectively support the form selection process for Drug Product Development, coupled with orthogonal techniques.

In particular, in house quantitative XRPD methods and how discovering of late appearing polymorphs has influenced the downstream medicine development is presented.

We will underline the needs to open the standard industrial approach to techniques with higher resolution (like synchrotron XRPD) with the objective to create new culture in the industry. The question: ‘Which API form is suitable for pharmaceutical development?’ is a crucial point that must have a solid and earnest answer

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