

Selective Applications of Thermal Analysis and Calorimetric Methods for Pharmaceutical Industry

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ABSTRACT

In the last decade, the genetic approaches as well as the screening and the synthesis tools increased considerably the number of drug candidates in explorative research. Development timelines however are still growing and the registration authorities put severe guidelines for safety and efficacy including outsourcing and supply-chain. Pharmaceutical industry is undergoing a period of intense transformation moving from the era blockbusterst to a personal medicine. The innovation technologies with “body on a chip” will strongly impact the pharmaceutical model but not in a next future.

At present, the major issues for the emergent poor soluble molecules are the manufacturing procedures, the biotransformation in situ and the stability due to the physicochemical characters of the solids.

As a consequence amorphous solid forms are newly introduced on the market and excipients analyzed for new drug delivery systems.

Essential questions are only answered by methods accessing basic thermodynamic rules such as Thermal Analysis and Calorimetric Methods and hyphenated techniques since several forms can exist depending on the parameters: temperature, pressure, humidity, solvents. Worldwide guidelines for the solid state of new entities and generics are still severe.

Chemical manufacture may change for elimination of toxic substances. Therefore the DSC purity method can validate the control and the stability testing as independent analytical tool.

Thermal analysis methods and Calorimetry are introduced in the pharmacopeia and different solid forms described in the monographs.

Some examples will demonstrate the essential place of Thermal Analysis and Calorimetric Method for pharmaceutical industry.

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