Denver X-Ray conference: Oral, podium presentation abstract

Title: In-situ, non-ambient method development for the solid state form identification of drug substance in drug product

Identification and characterization of a suitable solid state form is critical for the development of efficacious pharmaceutical drug products. XRPD often provides a straightforward analytical technique for qualitative form identification without the need for compound specific method development. In the case of complex polymorphic and solvated systems, where there is more than one process relevant solid form, the demand for more comprehensive identification methods that provide some degree of quantitative evaluation of phase purity via XRPD is ever increasing. Additional challenges are presented by the need to control form in drug product, where the presence of partially crystalline excipients makes peak association more complex. This work presents an in-situ approach, using non-ambient conditions, to develop a suitable XRPD method for qualitative form identification of the desired hydrate form, in drug product, while providing a limit of detection for the undesired, higher-order hydrate. The analysis is carried out using a Panalytical Empyrean system with Anton-Paar humidity module to control environmental conditions.