

## ☉ POWDER X-RAY DIFFRACTION

Powder X-Ray Diffraction Analysis (PXRD) is the primary tool for characterizing the crystalline and amorphous materials. Characterization and monitoring of solid-state properties of the active ingredients and excipients are fundamental elements of the pharmaceutical development since batch-to-batch inconsistency can cause crucial problems in the manufacturing of the pharmaceutical dosage form, the quality of the formulation, the bioavailability and drug stability.

Many new drug substances exist in different solid-state forms (polymorphs or solvates) that differ in their physical properties. Differences in these forms could/can affect the quality or performance of the new drug products. The application of systematic procedures and an increased number of experiments, combined with high resolution analytical equipment, helps in elucidation of the relevant polymorphic and pseudo-polymorphic forms in pharmaceutical development.

The scientists at Vimta have varied experience in solid state characterization with materials ranging from Active Pharmaceutical Ingredients to Finished Dosage Forms.

## ☉ SERVICES OFFERED

### SCREENING AND CHARACTERIZATION OF POLYMORPHS

- **Crystalline and Amorphous Forms**
  - Identification and characterization of polymorph in drug substance and drug product
  - Monitoring the stability of polymorph in drug substance and drug product
  - Method development and Validation for identification and quantification of polymorph in drug substance and drug product
- **Polymorph Screening**

80% of the Pharmaceutical compounds exhibit polymorphism. Choosing an appropriate form demands a thorough and systematic approach to screening and characterization.
- **Form Selection**
  - Salts
  - Crystalline forms
  - Hydrates & solvates
  - Non-crystalline ( Amorphous)

## ☉ INSTRUMENTATION

- **Powder X- Ray Diffractometer (PXRD) - Integrated Reflection – Transmission Geometry**
- Make : **Bruker d8 Advance**
- Capability to handle
  - Small sample quantities ( ~ 10 mg)
  - Direct Tablet analysis without grinding
  - Hygroscopic materials
  - Cytotoxic compounds
  - Emulsions / Suspensions / Gels

## THERMAL ANALYSIS

### ⊕ DIFFERENTIAL SCANNING CALORIMETRY (DSC) ANALYSIS

Thermal analysis has been an extremely important analytical tool in the Pharmaceutical Industry for more than 40 years. Differential Scanning Calorimetry (DSC) measures the rate of heat flow and is used to measure the heat of transition. As all the transitions in materials involve flow of heat (into the sample in endothermic events and out of the sample for exothermic events) DSC is the universal detector for measuring the wide variety of transitions in pharmaceutical materials.

The physical properties of amorphous structure are quite different from crystalline structure. Major differences include dissolution rate (Bio-availability), storage stability and hygroscopicity and the tendency to absorb the moisture or other solvents. It is therefore important to know if a drug or drug delivery system has an amorphous component.

### ⊕ SERVICES OFFERED

#### Analysis and Characterization of

- **Amorphous compounds**
  - Glass transition
  - Detection of amorphous material in semi-crystalline compound
  - Percentage of Amorphous content
- **Crystalline compounds**
  - Crystallinity
  - Melting and crystallization
  - Purity
  - Polymorphs
- **Drug –Excipient interaction**
  - Preformulation support
- **Thermal stability**

### ⊕ INSTRUMENTATION

- Differential Scanning Calorimeter (DSC)
- Make: **TA Instruments** (Modulated DSC)

## THERMAL ANALYSIS

### ⊖ THERMOGRAVIMETRIC ANALYSIS (TGA)

Thermogravimetric analysis (TGA) measures physical changes in materials. TGA provides quantitative measurement of mass change in materials associated with transition and thermal degradation. Vimta provides TGA analysis and expertise for characterization of hydrates, solvates and the thermal behavior of compounds.

Thermogravimetric analysis (TGA) uses heat to force reactions and physical changes in materials. TGA provides quantitative measurement of mass change in materials associated with transition and thermal degradation. TGA records change in mass from dehydration, decomposition, and oxidation of a sample with time and temperature. The thermogram data is a characteristic for specific materials and / chemical compounds due to unique physicochemical reactions occurring over specific temperature ranges and heating rates. These unique characteristics are related to the molecular structure of the sample.

### ⊕ SERVICES OFFERED

#### Analysis and characterization of

- Solvate / hydrate content
- Moisture content
- Decomposition analysis

### ⊕ INSTRUMENTATION

- Thermogravimetric Analyser (TGA)
- Make: **TA Instruments**

## ⊕ FT-RAMAN MICROSCOPE

Fourier Transform – Raman Spectroscopy (FT-Raman) is an important complementary tool for the solid state characterization of pharmaceutical solids and for the identification of the chemical structures. Spectroscopic investigations deliver chemical and physical information and combine high speed of analysis and the non-invasive measurements with high selectivity and sensitivity. The scientists at Vimta have experience with FT-Raman for characterization of pharmaceutical products ranging from Active Pharmaceutical Ingredients to Finished Dosage Forms.

## SCREENING AND CHARACTERIZATION OF POLYMORPHS

- **Crystalline Forms**
  - Hydrates
  - Solvates
  - Desolvated solvates
  - Anhydrous
- **Amorphous Forms**

## ⊕ SERVICES OFFERED

- Identification and characterization of polymorph in drug substance
- Identification of polymorphic form in Formulations
- Monitoring the stability of polymorph in drug substance and drug product
- Identification of raw materials and excipients
- Identification and spatial distribution of chemical components using Raman Microscope
- Distribution of Active Pharmaceutical Ingredient and Excipients in Solid Dosage Forms using Raman microscope and mapping

## ⊕ INSTRUMENTATION

- **FT-Raman Spectrometer with Microscope**
- *Make - Bruker*
- No sample preparation
- Non-contact (Non-destructive) measurement
- High specificity due to sharp and isolated Raman peaks
- Identification and quantification of Polymorphic Forms