SEQENS 'Lab

Analytical Solid-State Characterization Services

The need to investigate the solid-state properties of Active Pharmaceutical Ingredient (API) has become important in the pharmaceutical development industry. Physical properties can vary widely between batches, leading to batch to batch variability. Sometimes this can be attributed to difference in crystalline forms or mixtures of amorphous and crystalline.

Our highly skilled scientists can undertake studies that range from routine to highly complex and challenging characterization. We can perform physical and chemical characterization of API and Drug Product (DP) during all phases of the drug development process. A clear and concise report will be provided summarizing all findings and can be reviewed by Quality Assurance.

WHY CHOOSE SEQENS' LAB

- **Comprehensive and integrated offering to support pharmaceutical development (early up to late phase).**
- **Long-term expertise in Solid-State Characterization on site to support custom and proprietary Active Pharmaceutical Ingredient development.**
- **Comprehensive State of the art equipment allowing high capacity and fast turn-around.**
- **Development of in-house generic methods for a variety of techniques to eliminate the need to develop a method from scratch.**
- **Transfer of compendial or client-provided methods, as well as develop new methods when no current method exists.**
- **State of the art PAT (Process Analytical Technology) to support process optimization and scale-up (Blaze 900 in situ probe which provide chord length distribution, high resolution imaging and Raman characterization).**

Physical Characterization Testing Capabilities

XRPD characterization and testing (Empyrean Serie III, Malvern-Panalytical)

- Method development (Identification, limit test, etc.) of crystalline and amorphous ratio for APIs and excipients, depending on the individual composition

Particle Size Determination (Mastersizer 3000, Zetasizer Pro Red, Alpine e200 LS, Hosokawa)

- Particle size distribution by several techniques covering a broad range of sizes intervals ranging:
  - From 2 nm to 200 nm by Malvern Dynamic Light Scattering (Zetasizer Pro Red)
  - From 0.01 µm to 3,500 µm by Laser Diffraction (Mastersizer 3000) both in dry and wet mode with capability to determine the exact powder refractive index (using a refractometer instrument)
  - from 50µm to 3,500 µm by mechanical sieving and Alpine air jet sieving at various meshes (Alpine e200 LS)
- Capable of analyzing wet emulsion, suspension and bulk dry dispersion
- Determines diverse sample types: abrasive, fragile, cohesive or agglomerated

Morphological analysis (Morpho 4-ID with Raman, Malvern-Panalytical:

- Component-specific morphological descriptions of particulate blends
- Identification of particles through Morphologically-Directed Raman Spectroscopy
- Control both API and excipient particle size and shape during development, and throughout formulation and processing
- Simplification of deformulation challenges for Generics to support in vitro bioequivalence.
- Detect anomalies, contaminants and pinpoint process deviations during manufacturing

Surface Area (BELSORP-mini X, 2S)
- Calculates BET surface area (single or multipoint)
- Determines pore size and pore size distribution within 2 to 400 nm for macro, micro or mesoporous samples
- Predicts reactivity, dissolution and compactness

Microscopy (TM-1000, Hitachi and Nikkon Eclipse)
- Size and form analysis by Scanning Electronic Microscopy
- Polarised light microscopy (PLM)

Dynamic Vapor Sorption (DVS Intrinsic, SMS)
- Measures rate and ease of water permeation
- Measures water vapor sorption - desorption isotherm
- Measures effect of sample environment on crystallinity or amorphous content
- Determines changes in flow ability, compaction density and appearance

Differential Scanning Calorimetry (DSC3, Mettler)
- Determines phase and structural transition between -90 to 400°C
- Directly measures heat capacity
- Analyzes complex and overlapping thermal changes - modulated DSC capable
- Detects weak thermal changes

Thermogravimetric Analysis (TGA/DSC3+, Mettler)
- Measures the change in sample mass as a function of temperature and/or time
- Monitors moisture/Solvent loss (LOD on micro scale)
- Determines rate of chemical degradation at various temperatures
- Measures gas absorption-desorption

Hot-Stage microscopy (FP-80, Mettler)
- Allows to visually examine all kinds of thermal transitions when the sample is heated or cooled. Complementary to the thermal analyses (DSC and TGA).

Density and Flow properties (Tap density, Vankel and PF1, Sotax)
- Determination of bulk and tapped density
- Determination of powder flow ability
- Measure of repose angle

Pre-formulation Testing capabilities (Inform Platform)

- Allows for precise pH control and monitoring, enabling you to study dissolution under conditions that mimic in vivo conditions more closely that other systems.
- Provide biorelevant dissolution and solubility data (IDR, pKa, etc.)
- Determine characteristic absorption patterns of raw materials

Chemical Characterization Testing Capabilities

NMR (Bruker Avance III 400 Mhz equipped with a probe BBO400 Z108618_0277 / 5mm)
- Identifies chemical structure
- Quantification of residual solvents

Fourier Transform Infrared & Near-Infrared Absorption Spectroscopy
- Fingerprinting identification of known scan
- Identifies functional groups within the molecular structure
- Identifies resins and opaque/colored materials using photoacoustic scans

Ultraviolet-Visible Absorption Spectroscopy
- Determines characteristic absorption patterns of raw materials
- Used for qualitative detection, quantitative calculation and kinetic analysis

Equipment list

- Empyrean Serie III Malvern-Panalytical XRPD and CHC chamber (resolved temperature and relative humidity control)
- NMR Bruker Avance III 400 Mhz
- Mettler DSC3
- Mettler TGA/DSC3+
- FP-80 HT Hot-stage microscope, Mettler
- Malvern-Panalytical Particle Size Analyzer (LDPSD) Mastersizer 3000 (wet & dry)
- Malvern-Panalytical Morpho-Analyzer Morpholo M4 ID with Raman spectrocopy
- Hosokawa Alpine Air jet Siever
- Malvern-Panalytical DLS Zetasizer Pro Red
- Microtrac BET Belsorp-Mini X
- DVS Intrinsic (SMS)
- Optical Light Microscopy
- Hitachi TM-1000 Scanning Electron Microscopy
- Perkin-Elmer FTIR Spectrocopy
- Agilent Ultraviolet (UV) Spectroscopy
- Sotax Powder Flow Tester

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