

Solid-State Characterization

Eurofins BioPharma Product Testing can support solid-state characterization by offering method development and testing services on raw materials, active pharmaceutical ingredients (API), and pharmaceutical drug products through X-ray Powder Diffraction (XRPD), as well as Solid-State NMR (ssNMR).

Why Choose Eurofins BioPharma Product Testing?

All methods and testing are performed under GMP requirements and are FDA inspected.

Our state-of-the-art equipment allows high capacity, optimum sensitivity and fast turn-around-time, supporting development and product release.

Our broad scope of NMR capabilities and knowledge are centralized in the European Centre of Excellence for NMR in Oss, the Netherlands.

Solid-state NMR including 19F-NMR capabilities

We are one of few laboratories in the world that can provide ssNMR method development and testing services on ingredients, polymers and pharmaceutical drug substances and products with 19F-NMR application under GMP guidelines.

Solutions and Applications

- Identification and quantitation of polymorphs in APIs
- Identification and quantitation of polymorphs of APIs in dosage forms (depending on the drug loading)



- Evaluation of crystalline and amorphous ratio for APIs
- Spectroscopic confirmation of identity
- Characterization of polymers
- Patent infringement assessment

Equipment

400MHz WB Avance Bruker

- Our system is fitted with a dedicated 19F-NMR setup allowing 1H-19F CP-MAS experiment
- 10 positions sample changer
- Probes: 4mm MAS (1H, 19F, X), 7mm MAS (1H, X)

XRPD characterization and testing

We provide XRPD (X-ray Powder Diffraction) method development and testing services on raw materials, API and pharmaceutical drug products, under GMP guidelines.

Solutions and Applications

- Identification and quantitation of polymorphs in APIs
- Identification of API in Dosage Forms (depending on the drug loading)



- Quantitation of crystalline and amorphous ratio for APIs and excipients, depending on the individual composition
- Crystallographic confirmation of identity
- Rietveld Analysis to refine atomic structures and the composition of multiphase mixtures
- XRD phase analysis and pattern decomposition

Equipment

Empyrean Analytical

- System can measure both transmission and reflection geometry
- 45 position sample changer
- Fitted with a TTK (hotstage), which allows variable temperature experiments.

Comprehensive GMP Testing Services

Method Development & Validation • Release Testing • Raw Materials Testing
Cell Banking Services • Virology Services • Facility & Process Validation
Chemistry • Biochemistry • Molecular & Cell Biology • Microbiology
Stability Testing & Storage • Primary & Secondary Package Testing

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**BioPharma
Product Testing**