

Pharmaceutical Physical/ Chemical Characterization Services

Characterization testing is used to gain an understanding of the physical and chemical properties of pharmaceutical materials. During process and drug development, these properties can have an impact on the product's performance, ability to be processed, stability and appearance.

Eurofins BioPharma Product Testing provides cGMP compliant and non-GMP investigational characterization testing for pharmaceutical materials to support formulation, process development, quality control, GMP lot release testing, and investigational manufacturing troubleshooting. We have extensive experience with an array of product types from raw materials to active pharmaceutical ingredients and can accommodate virtually any product type.

Why Choose Eurofins BioPharma Product Testing?

Our extensive experience with a variety of techniques and sample types lends the ability to tailor the testing to meet specific client requirements at one testing location.

We have developed a host of in-house general methods for a variety of techniques to eliminate the need to develop a method from scratch. We can also follow compendial or client-provided methods, per cGMP, as well as develop new methods when no current method exists.

Sample Types

We have experience with a variety of sample types, including:

- Raw materials
- Development materials
- Intermediate in-process materials
- Active pharmaceutical ingredients
- Stability study samples
- Unknowns for identification or confirmation



Physical Characterization Testing Capabilities

Surface Area

- Calculates BET surface area: single or multipoint
- Measures the total pore volume or porosity as well as the pore size by gas absorption/desorption
- Krypton capable to measure surface area as low as 0.001 m²/g
- Predicts reactivity, dissolution and compactness

Dynamic Vapor Sorption

- Measures rate and ease of water permeation, hygroscopicity, deliquescence point, water activity
- 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 (DSC)

- 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)

- 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

X-ray Powder Diffraction (XRPD)

- Identifies crystalline or semicrystalline structure
- Analyzes degree of crystallinity, amorphicity
- Detects impurities

Particle Size & Zeta Potential

- Measures particle sizes from 0.01 μm to 3,500 μm , zeta potential from 0.3 nm to 10,000 nm
- Capable of analyzing wet dispersion and dry dispersion
- Determines diverse sample types: abrasive, fragile, cohesive or agglomerated

Physicochemical Properties

- Determination of Acid Dissociation Constant (pKa), Partition Coefficient (Log P), Distribution Coefficient (Log D)

Chemical Characterization Testing Capabilities

Fourier Transform Infrared & Near-Infrared Absorption Spectroscopy (IR [FTIR, NIR])

- Fingerprinting identification of known scan
- Identifies functional groups within the molecular structure
- Identifies resins and opaque/colored materials using photoacoustic scans

Carbon, Hydrogen & Nitrogen Analysis (CHN Elemental Analysis)

- Determines the mass fraction of Carbon, Hydrogen and Nitrogen content

Ultraviolet-Visible Absorption Spectroscopy (UV/VIS)

- Determines characteristic absorption patterns
- Used for qualitative detection, quantitative calculation and kinetic analysis
- Measures Molar Extinction Coefficient (MEC)

Metals Testing (ICP-MS)

- Trace level quantitation of most elements in liquid and solids

Mass Spectrometry (GC-MS, HPLC-MS)

- Measures mass of parent compound or daughter ions
- Accurate mass and fragmentation patterns
- Confirms molecular weight (identification)
- Evaluation of unknown purities

Instrumentation

- Micromeritics Tristar II Confirm Surface Area
- TA Instruments Q5000 SA Dynamic Vapor Sorption
- TA Instruments TGA Q500
- TA Instruments Discovery DSC 2500
- TA Instruments Nano DSC
- Malvern Mastersizer 3000 PSD
- Malvern Zetasizer Nano ZS90
- Malvern Zetasizer Ultra
- Bruker D8 Advance XRD
- Agilent 7900 ICP-MS
- Bruker Alpha II FTIR with Platinum Diamond ATR
- Thermo Nicolet 6700 FTIR
- Shimadzu UV-2700
- Agilent 8453/8454 UV-Vis
- 400MHz WB Avance Bruker with 19F-NMR setup
- 500MHz NMR Bruker Avance III, BBFO probe and TCI cryoprobe, SampleJet
- 400MHz NMR Bruker Avance III, BBFO probe (1H, 13C, 31P, 19F), SampleJet
- LC-SPE/NMR capability

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**