EXPERIC

The Experic Difference for Analytical Services

Experience It

Experic's analytical services provide powerful support at every phase of pharmaceutical development and manufacturing.

Our experienced analytical team empowers your ability to make informed, critical decisions about your product and process and meet your regulatory requirements.

Solutions That Meet Your Needs

With a team of experienced scientists and a robust toolbox of analytical techniques, Experic can support the total life cycle of your oral solid dose and/or inhalation pharmaceutical products. Our laboratory staff provides comprehensive analytical solutions to support the entire spectrum of development and manufacturing:

- Raw material testing to establish identity, purity, and potency before materials are used in production
- Formulation and process development activities
- Development and validation of analytical techniques to ensure accuracy, precision, specificity, and robustness of the methods used to test pharmaceutical products, including identification and quantification of impurities, degradation products, and other critical quality attributes
- Analysis of in-process samples for process control
- GMP release at clinical scale and commercial products to ensure compliance with regulatory standards

Based on a consultation with you and your team, Experic project specialists will recommend phase-appropriate analyses to support patient safety, develop efficient manufacturing processes, and prepare CMC data for examination by regulatory authorities. Services are available as part of a complete development program or as stand-alone services.

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Our laboratory includes 3,800 square feet of GMP analytical lab space and a team of seasoned laboratory scientists. It is designed for a broad range of analytical techniques and outfitted with equipment to support the development and manufacture of a variety of drug delivery modalities, including dry powder inhaled (DPI) therapeutics.

The laboratory's more extended capabilities include the analysis of products requiring special environmental controls for storage, as well as physiochemically hygroscopic, light-sensitive materials and controlled substances. Laboratory operations comply with 21 CFR Part 211, 21 CFR Part 11, EudraLex Volume 4, and ICH Q10.

General Analytical Capabilities

- Technology/method transfer
- Method feasibility, development, and validation
- Cleaning verification and validation
- Comparator testing
- Release testing of raw materials, API, and finished products
- Stability assessments aligned with ICH Q1A(R2) guidance for long-term, intermediate, and accelerated conditions to assess shelf life and storage conditions
- Compendial testing (USP, Ph. Eur., BP, JP)
- Microbial testing to ensure product safety and compliance with regulatory standards

Stability Storage

- 25˚ C/60% RH
- 30˚ C/65% RH
- 40˚ C/75% RH

Analytical Support for Dry Powder Inhalation Products

- Aerodynamic Particle Size Distribution (APSD)
- Blend uniformity
- Cascade impaction (NGI)
- Content uniformity
- Delivered dose uniformity
- Particle morphology
- Powder flow/rheology determination (FT4)
- Tap density testing
- X-ray diffraction

Testing Methods & Equipment

- Assay
- Blend uniformity
- Cascade impaction
- Content uniformity
- Disintegration
- Dissolution
- Residual solvents
- Gas chromatography (GC)
- High performance liquid chromatography (HPLC) with UV/VIS and RI detection capabilities
- ID testing
- Loss on drying
- Microbiological testing
- Moisture testing/Karl Fischer (KF)
- Water activity
- Particle size distribution
- pH
- Powder rheology
- Related substances
- Residual solvents
- Residue on ignition
- Sieve analysis
- UV/Vis Spectrophotometric analyses
- Fourier Transform Infrared Spectroscopy (FTIR)
- Differential scanning calorimetry (DSC)

About Experic

Experic, a contract development and manufacturing organization (CDMO) and pharmaceutical supply services company, supports every phase of a product's life cycle from conception to clinical and commercial scale, across a range of dosing and packaging formats, including tablets, capsules, and low dose dry powder inhalation. From our state-of-the-art, Class A cGMP facility, we manage global delivery of the highest quality products, even for expedited projects, while providing unparalleled knowledge, expertise, and customer service.

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