Analytical Services

Ensuring quality, safety and efficacy

SmaBio Labs offers comprehensive analytical services that support our customers from drug discovery through commercial product release. Our services include method development, validation, and transfer, as well as in-process control, release tests, and stability studies. Our analytical teams are equipped to assist throughout the drug development process, characterizing drug substances, supporting formulation development and drug discovery, and managing clinical trial materials for both early and late phase studies.

Techniques and Tools

Utilization of LC, GC, LC/MS, and GC/MS for comprehensive analysis.

Method Development and Validation

Providing robust analytical methods tailored to your needs, from early development to commercial release.

Phase-Based Validation

Ensuring compliance with FDA, EMA, and ICH guidelines through tailored validation studies.

Release Testing

Conducting thorough testing of drug substances and drug products using validated methods.

Release Testing and Stability Studies

Ensuring product integrity and compliance through meticulous testing and well-defined stability studies.

Stability Studies

Following ICH/FDA/EMA guidelines to design stability protocols, including various testing conditions.

Advanced Techniques

Employing LC/MS, GC/MS, NMR, FTIR, and UV for accurate impurity identification and quantitation.

Identification and Quantitation of Impurities

Identifying and quantifying impurities to ensure product safety and efficacy throughout the development process.

Risk Assessment

Evaluating the impact of impurities on product safety and effectiveness.

Extractables & Leachable

Offering comprehensive assessments to ensure safety and compliance regarding extractables and leachables.

Standard & Customized Studies

Utilizing LC-QTOF and GC-QQQ for detailed E/L analyses.

Risk Management

Assisting in the evaluation and mitigation of potential risks from E/L.

Reference Standards

Providing essential services for the qualification and management of reference standards during drug development.

Qualification Services

Ensuring reference standards are well characterized and analyzed for research phases.

Storage and Management

Helping manage the use and storage of reference standards effectively.

Raw Material Testing

Guaranteeing the quality and safety of raw materials used in pharmaceutical manufacturing.

Comprehensive Testing

Covering chemical testing, identification, and outsourced microbiological testing.

Stability Testing

Ensuring raw materials maintain their quality and efficacy throughout their use.

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SmaBio LABS