Renejix

Small Molecule Analytical Services

A Partner With Expertise Renejix's small molecule analytical team has developed and applied thousands of analytical methods to progress drug candidates. All stand-alone small molecule analytical projects are managed through our Happauge Industrial Park, NY and Central Islip, NY locations. Leverage Renejix's network of over 400+ researchers in 3 countries, providing a single-site solution, with the scientific resources of a multinational research organization.

- Hundreds of clients supported, from start-ups to large pharma
- Industry-renowned experts
- Dedicated project management team throughout project lifecycle
- Dossier-ready reports

Broad Suite Of Services We support GMP, GLP and characterization studies for drug substance, drug product and intermediates. We work on controlled drug substances from early preclinical through clinical and commercial stages, Renejix delivers a single-provider solution for a wide variety of challenges:

- Method development, optimization, validation & transfer
- Stability testing and storage
- Preformulation & solid state
- Elemental impurities / Inorganics
- Organic spectroscopy
- Compendial analysis

Strength In Stability With over 30,000 ft^3 of fully-mapped and qualified stability chambers, dedicated study coordinators, continuous monitoring and validated electronic scheduling / reporting, we can support all study types and time points as well as provide the stability testing needed to support a product throughout its lifecycle.

SMALL MOLECULE ANALYTICAL SERVICES

Renejix ANALYTICAL

Preclinical → Ind → Phase I → Phase II → Phase III → FILE NDA → Phase IV/ COMM

Preformulation & Solid State

Organic Spectroscopy

Microbiology

Method Development & Validation

Stability Testing & Storage

Elemental Impurities/Inorganics

Compendial Analysis

Extractables & Leachables

PREFORMULATION & SOLID STATE

Preformulation Studies

Solubility and stability (pH, O_2, T, RH)

Physical properties evaluation

- Hygroscopicity
- Crystallinity
- Thermal

Excipient compatibility

Salt Screening & Selection

High-throughput capabilities

Scale-up capabilities (up to 2L)

Detailed candidate salt evaluation

Crystal-Form Screening & Selection

Focused and comprehensive screening

Phase-diagram

Polymorph control

Co-Crystal Screening

Milling, solution & slurry modes

Crystal engineering

Crystallization Screening

Crystallization of amorphous API

Chiral resolution

Process Development

ORGANIC SPECTROSCOPY

Techniques

NMR (Nuclear Magnetic Resonance)

- qNMR (Quantitative NMR)

LC MS / LC MS-MS

- QTOF, triple quad, ion trap

FTIR / DSC / TGA / UV-Vis / LOD / ROI

Karl Fischer / Moisture content

Impurity Identification

Molecule weight / Accurate mass

Fragment pattern interpretation

Impurity enrichment / isolation

Genotoxic impurities

Routes of formation

Reference Standards

Identity & purity

Reference standard qualification

Other Manufacturing Support API release, quantity, and ID

Quantitation of genotoxic impurities

Excipient/compendial release

Routine testing & process support

MICROBIOLOGY

USP testing for various product types

Qualification & Testing

Sterile and Non-Sterile Products

Oral, Blow-Fill-Seal

Combination products

Endotoxin

USP<85>

Gel Clot

Kinetic / Turbidimetric

Chromogenic **Microbial Enumeration** USP <60>, <61>, <62>

Sterility

USP<71>

Utilizing Isolator Technology

METHOD DEVELOPMENT & VALIDATION

API and drug product (all dose forms)

Method Development & Capabilities

HPLC/UPLC/GC assay and impurities Dissolution:

- Immediate release
- Sustained release
- Extended-release

Residual solvents

Cleaning verification

Physical methods:

- Moisture
- HIA
- CE
- UV Assay

Method Validation

Phase-appropriate validation

Method validation remediation

Method Optimization Method Transfer

Side-by-side comparison

Transfer of elements of validation

Method Troubleshooting

STABILITY TESTING & STORAGE

Stability Storage

Over 30,000 ft^3 of mapped/ qualified chambers

Temperature range: -80°C to 60°C

Humidity range: 20% to 75% RH

Redundant power, water & air systems

ICH photostability option 2

WHO, ASEAN, ICH & custom chambers

Thermal cycle & freeze/thaw exposures

Dedicated/qualified engineering group

Stability Testing

Release & stability testing

- Clinical
- Comparator
- Registration
- Commercial

Dose dumping studies

In-use studies

In-vitro feeding tube studies

Safety (categories 1-4)

Controlled substances (schedule I-IV)

ELEMENTAL IMPURITIES/INORGANIC

Q3D Risk Assessment

Risk assessment testing

- GMP/non-GMP screening packages

Risk assessment regulatory reports

Regulatory consulting

Compendial Metals Testing

USP / ACS / Ph Eur

Techniques

ICP-MS

ICP-OES

GFAA

FAA

CVAA

Routine Testing Support

Process Chemistry Support

Metal catalyst analysis

Manufacturing component screening

Inorganics Extractables & Leachables

Inorganic impurities Q3D-aligned

USP <661.1> Extractable Metals

COMPENDIAL ANALYSIS

USP / ACS

Ph Eur / BP

JP / JPE

Instrumentation

Malvern Mastersizer 3000 / DLS HPLC

various detection capabilities GC, GC-MS

Verification of Method Transfer

Residual Solvents per USP <467>

Screening

Limit tests Quantitative tests **Component testing**

EXTRACTRABLES & LEACHABLES

Extractables Characterizations Container closure systems

Single-use items

Manufacturing

Leachable Migration Studies

Drug Product Drug Substance

In-process testing / In-use testing

Leachables Method Development & Validation

ICH Guidelines

Volatile, semi-volatile & non-volatile

Nitrosamines

PAHs

Fatty acids

Leachables Stability/Release

Drug Product

Drug Substance

Container closure materials (release only)

Discover more solutions
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