Pharmaceuticals - your end-to-end analytical partner

We're here to help you navigate the scientific, technical and regulatory roadblocks to ensure the continued success of your product. With more than 30 years of analytical excellence and cutting-edge cGMP laboratory services, we have the insight, experience and capabilities to support you at every stage of your development and manufacturing process.

1

RAW MATERIALS TESTING

- Full Pharmacopeial testing (EP, BP, USP, JP and CP) including traditional wet chemistry and particulate techniques
- Ninhydrin positive substances
- Method verification
- Stability testing
- Characterisation: Assay, related substances, physical testing, spectroscopic (NMR, FT-IR), structural confirmation
- Contaminants and impurities

2

FINISHED PRODUCT RELEASE

- Dissolution
- Inhalation NGI: delivered dose uniformity, APSD
- Method development, validation and routine testing (ICH Q2 R1)
- Method transfer
- Characterisation: Assay, related substances, physical testing, spectroscopic and structural confirmation
- Trace element analysis (USP <232> <233>) (ICP-OES, ICP-MS)
- Degradants, contaminants and impurities
- Chromatography capabilities (including ion chromatography)

3

PACKAGING TESTING

- Bespoke extractables and leachables studies
- Container testing
- Integrity and characterisation testing (glass vials, stoppers)
- Syringe functionality and compositional testing
- Container closure testing
- Routine sterility testing
- Penetrability (IV bags, stoppers)
- Fragmentation
- Device characterisation (inhalers)

4

ICH STABILITY STUDIES

- Storage (variety of conditions) for shelf-life assessments
- Photostability (ICH Q1 B)
- Transport/cycling studies
- Protocol creation

5

PRODUCTION SUPPORT

- Cleaning validations
- Foreign body identification
- Cleaning verification
- Contaminant identification and characterisation
- Consultancy

6

TROUBLESHOOTING & INVESTIGATIONS

- Nitrosamine testing
- Contamination Identification
- Fraud/counterfeit investigations
- Microbial contamination and identification to species levels (MALDI-TOF)
- Method redevelopment and validation
- Impurity isolation, sample purification and ID (preparative LC, LCMS and NMR)
- Toxicological support
- Priority Response Service
- High sensitivity analysis (IC, GCMS and ICP-OES)

For more details please contact RSSL
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