









SUBSTANCE









World's largest network of bio/pharmaceutical GMP product testing labs

Enabling companies to advance resources from development through commercialization

Ensuring regulatory compliance, cost effectiveness and timeline adherence

Our specialized pharma product testing services includes but not limited to below services:

Method Establishment

Method Development And Validation

- Method Validation
- Method Verification
- Forced Degradation Study

Method Transfer

- Direct Method Transfer
- Indirect Method Transfer

Trace Analysis

Nitrosamines

• Test all seven FDA identified drug product impurities using single method by LCMS/MS

Genotoxic Impurity

Detect genotoxic impurities regardless of mechanism using GC-MS/LC-MS

Residual Solvents

- · Check residual solvents level in your drug product or drug substances using GC-HS
- Get accurate levels of organic volatile chemicals that are used or produced in the manufacture of drug substances or excipients, or in the preparation of drug products

Elemental Analysis

- · We offer elemental analysis using ICP-MS for trace metal analysis
- ICP-MS is used to assay trace and ultra-trace elements at part per billion (ppb) levels

Quality Control

Batch Release Tests

- Routine Analysis
- Stability Sample Analysis

Raw Material & Excipients

- Method development/verification of inhouse & IP/BP/USP pharmacopeial methods with batch analysis
- Molecular weight determination by HPLC with RI detector <621>

Packaging Testing

Moisture vapor transmission rate (MVTR)

Physical Characterization

Particle Size Distribution

- Wet method
- · Dry method

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