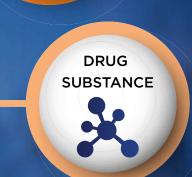




**INJECTABLES** 















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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