intertek
Total Quality. Assured.

GMP & CMC Laboratory Services

Pharmaceutical Services India

Analytical Testing, Auditing and Process & Powder Safety Testing

US FDA, MH-FDA, CDSCO, cGMP, GLP & NABL Certified Laboratory

intertek.com/pharmaceutical/mumbai-india/

Accelerating Development. Ensuring Compliance.

Comprehensive Pharmaceutical Testing, GMP Auditing & Process & Powder Safety Testing

Intertek Pharmaceutical Services India helps pharmaceutical companies accelerate product development, assure quality, and achieve global regulatory compliance through analytical testing, GMP auditing, and process safety expertise.

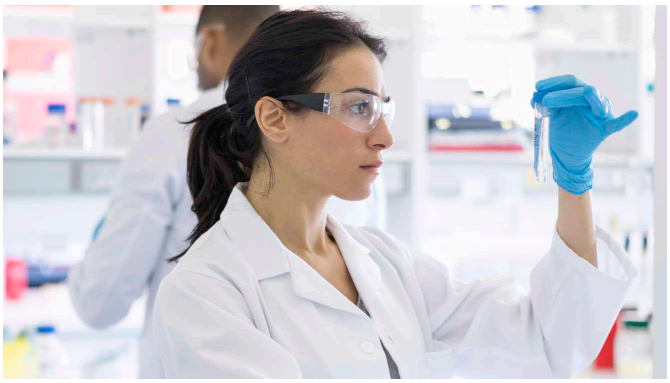
From our US FDA-audited, NABL-accredited and GLP-certified laboratory in Mumbai, we deliver high-quality scientific data, regulatory insight, and rapid turnaround to support every stage of the product lifecycle. Our experts help minimise manufacturing and powder-handling risks while providing the analytical and quality assurance services needed to bring products to market with confidence.

Our specialist teams provide expertise across three core service areas:

Pharmaceutical Analytical Testing
Comprehensive analytical testing that support product development, quality control, regulatory submissions, and commercial release.

Process Safety & Dust Hazard Evaluation
Specialist testing services that identify thermal, electrostatic, and combustible dust hazards, helping to improve process safety and reduce operational risk.

GMP Audits & Quality Assurance
Flexible GXP auditing services that strengthen supplier oversight, ensure regulatory compliance, and enhance quality throughout the supply chain.



Why Partner with Intertek Pharmaceutical Services India?

Globally Accredited Quality Systems - MH-FDA approved, CDSCO compliant, GLP certified, NABL accredited. All instruments are 21 CFR Part 11 compliant.

Over 15 Years of Regulatory & Scientific Expertise - We are trusted by major national and international pharmaceutical companies for regulated-market analytical support and compliance-driven testing.

Advanced Analytical Technology Platform - Our analytical laboratories have a broad scope of instrumentation including LC-MS/MS, GC-MS/MS, GC-MS/MS TQD, ICP-MS, Ion Chromatography, HPLC, FTIR and more.

Strong Presence in India - Intertek serves customers across all industry sectors and regions in India from 21 labs and 15 offices.

Global Pharmaceutical Lab & Regulatory Network

Backed by Intertek's international GXP laboratory network, we provide support across the pharma value chain.

Discovery & Development | **Preclinical Development** | **Clinical Development** | **Commercialisation & Post-market Monitoring**

- GLP / GCP bioanalytical services & biomarkers
- GMP & CMC laboratory services, QC raw materials & GMP batch release testing
- Inhaled & Nasal drug development
- Formulation, ICH Stability and clinical trial material manufacturing
- Extractables/Leachables and container closure integrity testing
- Toxicology and impurity risk assessment
- CMC advisory & guidance
- Supplier GXP auditing
- Process, facility and equipment calibration

Science. Quality. Assurance.

Pharmaceutical Analytical Testing

We provide comprehensive analytical support for developers and manufacturers of pharmaceutical and biopharmaceutical products, APIs, excipients, packaging systems, and raw materials. Our Mumbai laboratory is a US FDA-audited, MH-FDA-approved, CDSCO-compliant, cGMP-compliant, GLP-certified and NABL-accredited Laboratory.

Our scientists use advanced instrumentation and validated methodologies aligned with global pharmacopoeias and ICH guidelines.

- Method development & method validation
- Extractables & leachables studies (USP, PQRI, ICH, ISO 10993-18)
- Nitrosamine and genotoxic impurity testing (LC-MS/MS & GC-MS/MS), nitrate and nitrite content testing
- Impurity Identification using NIST spectral libraries
- Glass delamination and container closure studies
- Drug product and drug substance assay
- Batch release testing (API & finished dosage forms)
- Anion analysis by ion chromatography
- Residual solvent analysis (GC-MS/GC-HS-MS)
- Elemental Impurity testing as per ICH Q3D (ICP-MS)
- Dissolution and disintegration testing (USP Apparatus I & II)
- Stability studies (ICH Q1A/Q1B compliant)
- Raw material testing for pharma, food and chemical industries

Pharmaceutical & Healthcare Audits

We provide independent auditing solutions to strengthen quality systems, supplier oversight, and regulatory readiness.

As an experienced audit partner, we help organisations gain visibility across their supply chains, identify risks early, and improve overall quality performance.

Our pioneering "shared audit" approach further enhances efficiency by combining multiple sponsor requirements into a single supplier audit, reducing duplication, saving time, and lowering costs while minimising disruption for audited sites.

Auditing - Key Features & Benefits

- **Comprehensive regulatory coverage:** Audits conducted against GxP standards (GLP, GCP, GDP and GVP), and sector-specific guidelines such as IPEC, ISO 22716, ISO 15378, EFfCI, and EHPM.
- **Global expert auditor network:** Our senior auditors are located in your regions and have international experience providing consistent, high-quality assessments aligned with current regulatory expectations.
- **End-to-end supply chain oversight:** Evaluation of APIs, excipients, packaging materials, manufacturing sites, analytical laboratories, CROs, logistics providers, IT, and other critical service providers.
- **Flexible audit models:** Options include private audits, shared audits, remote/ virtual audits, internal audit support, and audit report purchasing for faster supplier qualification.
- **Shared audit efficiency benefits:** Consolidates multiple customer audit requirements into a single audit, reducing supplier burden, minimising repeated site visits, improving resource efficiency, and lowering overall audit costs.

Process Safety & Powder (Dust) Hazard Testing

With over a decade of experience, we help pharmaceutical companies worldwide identify and mitigate risks associated with powders, chemicals, and manufacturing processes. Our process safety specialists combine rapid turnaround with dedicated support to define the safety controls needed to minimise hazards in powder handling and processing.

We deliver a comprehensive range of testing and assessment services, including:

Thermal Stability and Chemical Reaction Hazard Testing

- Differential scanning calorimeter (DSC)
- Accelerating rate calorimetry (ARC)
- Thermal screening unit (TSU)
- Reaction calorimeter
- Reaction calorimeter with gas evolution data
- Flammability limits (UFL & LFL)

Electrostatic hazard , Dust Explosion & Dust Ignition/flammability Behaviour

- Grewer oven test
- Lutolf oven – DTA open cup
- Burning test
- Dust explosion modified hartmann test
- Dust explosion severity testing (Kst / Pmax)
- Minimum explosible concentration (MEC)
- Limiting oxygen concentration (LOC)
- Ignition temperature for airborne dust cloud (MIT)
- Dust layer ignition
- Gas evolution test
- Minimum ignition energy (MIE)
- Bulk powder resistivity
- Charge decay analysis
- Fall hammer test
- Friction test
- Go/No-Go testing as per ASTM 1226

Process Hazard Analysis

- HAZOP study
- Root cause analysis
- Dust hazard assessment

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