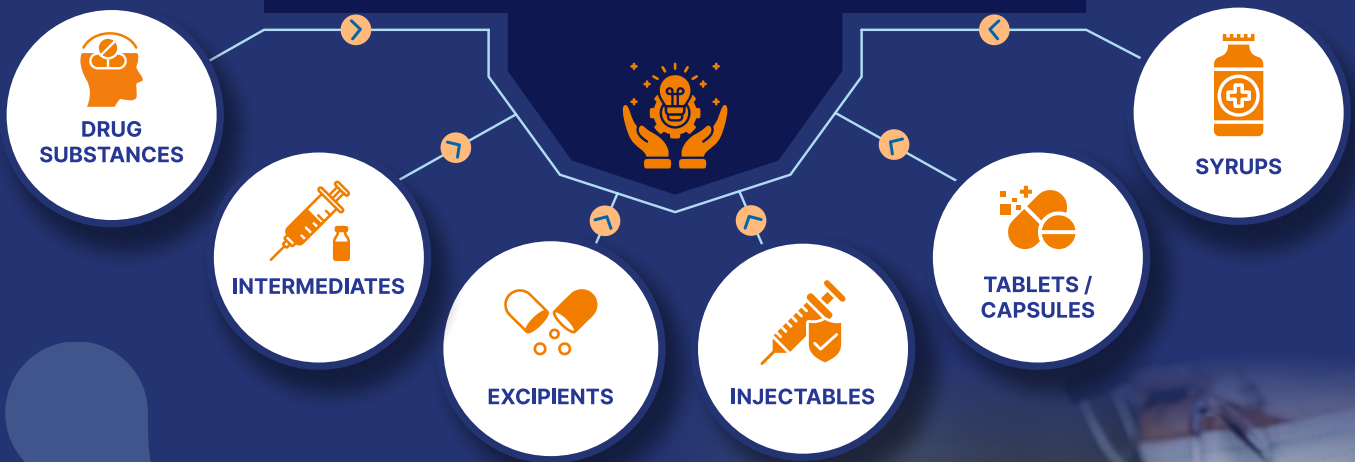


**ACCURATE, QUICK & GLOBALLY ACCEPTED  
PHARMA PRODUCT TESTING  
SOLUTIONS**



**FDA**  
Inspected

**Health Canada**  
Inspected

**ISO**  
17025:2017

**CDSCO**  
Ministry of Health & Family Welfare, Government of India

**cGMP**  
COMPLIANT

**NABL**

**PMDA**  
KARNATAKA

**PMDA**  
Accredited



World's largest network of GMP testing labs - 45+ facilities across 20+ countries ensuring harmonized testing and global regulatory acceptance



End-to-end testing solutions to accelerate your product's path to market



Precision-driven testing that ensures regulatory compliance with cost-effective, timely execution

# OUR SPECIALISED PHARMACEUTICAL PRODUCT TESTING SERVICES INCLUDE

## METHOD DEVELOPMENT AND VALIDATION

(USP<1225>, USP<1226>, ICH Q1B, ICH Q2)

- Method development, method validation, method verification
- Forced degradation studies

## METHOD TRANSFER (USP<1224>)

- Direct and indirect method transfer

## NITROSAMINE IMPURITY TESTING

- Testing for generic impurities and nitrosamine drug substance related impurities (NDSRIs)
- Platforms: LC-MS/MS, GC-MS/MS, Q-ToF

## GENOTOXIC IMPURITY EVALUATION

- Sensitive detection using LC-MS or GC-MS as per ICH M7

## BATCH RELEASE TESTING

- Routine analysis of raw materials, excipients, drug substances, and drug products

## EXTRACTABLES & LEACHABLES (E&L) STUDIES (USP <1660>, <1663>, USP <1664>, PQRI)

- Container closure system
- Process components
- Glass delamination study
- Drug product testing
- Medical device chemical characterisation (ISO 10993-18,10993-12)

## STABILITY STUDIES (ICH Q1A (R2))

- Accelerated, intermediate, long-term storage and analysis

## MICROBIOLOGY TESTING SERVICES

- Microbial enumeration test (USP <60, 61 & 62>, Ph.Eur < 2.6.12> & < 2.6.13>)
- Bacterial endotoxin test (USP <85>, Ph.Eur. <2.6.14> and JP <4.01>)
- Sterility test (USP<71>, Ph.Eur < 2.6.1>, and JP <4.06>)
- Antimicrobial effectiveness testing (USP <51>, Ph.Eur < 5.1.3>)
- Antibiotic microbial assay (USP<81>)
- Disinfectant efficacy test (USP<1072>)

## RESIDUAL SOLVENTS (ICH Q3C)

- Accurate quantification of volatile chemicals
- Testing via GC-MS

## ELEMENTAL IMPURITY ANALYSIS (USP<232>, USP<233>, USP<730> & ICH Q3D)

- Trace metal analysis using ICP-MS for accurate quantification of elemental impurities
- Detection at part-per-billion (ppb) levels in line with global regulatory requirements
- Reverse engineering studies to identify and quantify unknown elements in formulations

## RAW MATERIALS AND EXCIPIENTS

- Method development/verification of in-house and pharmacopoeial (IP/BP/USP) methods
- Detectors: UV/PDA, RI, ELSD

## PHYSICAL CHARACTERISATION (USP <786> <941>)

- Particle size distribution (wet and dry method)
  - Powder X-Ray Diffraction (pXRD) analysis



**EUROFINS BIOPHARMA PRODUCT TESTING  
INDIA PRIVATE LIMITED**

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