eurofins

BioPharma Product Testing

ACCURATE, QUICK & GLOBALLY ACCEPTED PHARMA PRODUCT TESTING SOLUTIONS

- DRUG SUBSTANCES
- INTERMEDIATES
- EXCIPIENTS
- INJECTABLES
- TABLETS / CAPSULES
- SYRUPS

FDA Inspected | Health Canada Inspected | ISO 17025:2017 | CDSCO | cGMP COMPLIANT | NABL | Drugs Control Department 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-HS

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

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