



Pharma Lab & Facility

Shiva Analyticals is proud to be a part of the Cotecna Group. Shiva Analyticals (India) Private Limited is one of the foremost analytical testing labs in India, providing solutions across diverse industries; Pharmaceuticals, Food & Beverages, Minerals & Ores, Fuels & Oil, Industrial Hygiene and Material testing.

ACCREDITATIONS & RECOGNITIONS

- > NABL /ISO/IEC 17025: 2017
- > ISO 9001:2015
- > ISO 45001:2018

Shiva Analyticals completely dedicated & independent Pharma Lab with State of the Art facility is amongst the first few labs globally as "e-Lab" with all instrument connectivity on server and 100% compliance to 21CFR part 11 and cGMP. The data generated during entire process of sample analysis are audit trialable with auto backups at multiple server locations.

Shiva Analyticals Pharma Lab upgraded facilities with new instruments, big pool of reference standards & consumables ensures better analysis feasibilities and faster deliveries. Shiva Analyticals Pharma Lab through cutting edge technologies with experienced and well trained team is dedicated to provide you accurate and precise results.

Shiva Analyticals Pharma Lab has the following Accreditations, Certificates and Approval:

- > ISO/IEC 17025:2017
- > Facility audited by USFDA
- > ISO 9001 : 2015 Certified
- > ISO 45001: 2018 OHSMS Certified
- > Approved by Karnataka Drug Control Department
- > Approved by Central Drugs Standard Control Organisation

Equipped with sophisticated instruments like LC-MSMS of Waters TQS Micro, LC-MSMS of Waters TQ-XS, GC HS-MS, GC-MSMS with TCD, ICP MS, ICP OES, AAS, IC Dionex ICS 5000+, GC-Head Space, GC-Dual FID Autosampler/Manual, HPLC with UV-VIS, RI, DAD, FLD, and VWD detectors, UV-VIS Spectrophotometer, ATR-FTIR, Particle Size Analyzer – Horiba LA 960 V@, Dissolution test apparatus, etc.

1. Analytical R&D

Shiva Analyticals Pharma Lab dedicated team excels in the following R&D activities:

- > Analyticals Method development and validations:
 - * Stability indicating assay
 - * Related substances/Degradation Products
 - * Enantiomeric purity
 - * Residual solvents/Organic volatile impurities
 - * Wet chemical analysis
 - * Dissolution
 - * Content uniformity
- > Cleaning validations
- > Impurity identification by LC-MS/MS and GC-MS/MS
- > Dissolution profiling

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- > Stability Studies for Drug products as per ICH Guidelines
 - * Long-term stability
 - * Intermediate stability
 - * Accelerated stability
- > Method development and validations for heavy metals by ICP MS, ICP OES and AAS
- > Method development and validations for Residual Genotoxic impurities by GC MSMS, LC MSMS.

2. Extractable and Leachable Studies

Extractable and Leachable Studies on Primary, Secondary & Tertiary packaging components including Gum and Ink migrations Studies for:

- > Ophthalmic Solutions
- > Inhalation Aerosols and Sprays
- > Injections and Injectable Suspensions
- > Inhalation Powders & Solutions
- > Sterile Powders and Powder for Injection
- > Transdermal Ointments and Patches
- > Topical Powders, Solutions & Suspensions
- > Topical and Lingual Aerosols
- > Oral Powders, Solutions & Suspensions
- > Oral Tablets and Oral Hard & Soft Gelatin Capsules

3. Chemical Testing

Shiva Analyticals Pharma Lab partners in analytical and compendial analysis of

- > Excipients
- > Raw materials
- > Intermediates
- > Finished Formulations

4. Contaminant Testing

- > Elemental impurities analysis by ICP MS, ICP OES and AAS as per ICH Q3D
- > Analysis of Genotoxic impurities by GC MSMS, LC MSMS
- > Analysis of Nitrosamine impurities by GC MSMS, LC MSMS
- > Residual Solvents and Organic Volatile Impurities
- > Residual Ethylene Oxide, Ethylene Glycol & Ethylene Chlorohydrin
- > Quality testing of Compressed Air/Nitrogen
- > Water Testing -Raw/Processed/Drinking/Effluents

5. Microbiology

- > Microbial Assay Method Validations
- > Microbiological tests as per the Harmonized protocol USP
- > Sterility Testing
- > Invitro test for Bacterial Endotoxins by LAL Test or Gel-Clot method
- > Preservatives efficacy / Antimicrobial Effectiveness testing
- > Total aerobic microbial count (Plate count & Fungal count)
- > Tests for micro-organisms like E. Coli, Salmonella, Pseudomonas aeruginosa, Staphylococcus aureus & Clostridium perfringens etc.
- > Multivitamin assays and Antibiotic assays
- > Lactobacillus spores count
- > Hygiene/Clean Room audits

6. Medical Devices & Packaging Materials:

- > Residual Ethylene Oxide, Ethylene Glycol & Ethylene Chlorohydrin
- > Elemental Impurities analysis
- > Global & Specific Migration
- > Alkalinity of Glass Containers
- > Identification of polymeric packaging
- > Residual Gases in packaged products
- > Bioburden Test
- > Sterility Test

7. Facilities for Herbal Medicines and Food Supplements:

- > Testing is carried out as per WHO, Canadian, Indian and European Guidelines for the following:
- > Toxic Metals
- > Pesticide Residues
- > Microorganisms
- > Residual Solvents and Organic Volatile Impurities
- > Aflatoxins

8. Ayurvedic Products analysis as per AYUSH

Quality is our mind-set and not limited to meeting the regulations. Please get in touch with us at info@shivaanalyticals.com to experience an unmatched Customer friendly services.