Pharmaceutical Analysis and Facility

Eureka Analytical Services (Eureka) is a provider of leading testing, inspection and auditing services for food, agricultural commodities, feed, nutraceuticals, pharmaceuticals and the environment, with labs in **Bangalore, Kundli-Delhi, Unjha-Gujarat, Guntur-Andhra Pradesh, Bramer, Kerala** and **Mumbai**.
Eureka is the exclusive partner lab in the Indian subcontinent of the GBA Group, headquartered in Hamburg, Germany.

ACCREDITATIONS & RECOGNITIONS

- **ISO/IEC 17025:2017**
- **Food and drugs administration, Haryana**

Quality is paramount in the pharmaceutical industry, as people's lives are directly dependent on the quality of medicines given to them for the treatment of diseases. This highlights how important it is to have a reliable partner for the testing and certification of pharmaceutical products and their ingredients.

Eureka's entirely dedicated and independent Pharma Lab with a state-of-the-art facility is one of the first few labs in the globe to have an "e-Lab" with all instrument connectivity on the server and 100% compliance with 21CFR Part 11 and cGMP. The data created throughout the entire sample analysis process is audit-trialable and has automatic backups on several servers. With the addition of new instruments, a sizable collection of reference standards, and consumables, Eureka Labs enhanced its facilities and ensured more accurate evaluation capabilities and rapid deliveries. Our team of experts and professionals is committed to offering you reliable and precise outcomes with cutting-edge technologies.

Equipped with sophisticated instruments like **GC, GC-MS, LC-MS-MS, GC-MS-MS, GC-HS-MS, ICP MS, ICP OES, HPLC, UV-VIS Spectrophotometer, FTIR, ELISA, PCR, NMR** and much more accordingly.

1. ANALYTICAL R&D

- Analytical Method Development and Validation
  - ⟶ Stability-indicating assay
  - ⟶ Related substances or degradation products
  - ⟶ Enantiomeric purity
  - ⟶ Residual solvents or organic volatile impurities
  - ⟶ Wet chemical analysis
  - ⟶ Dissolution
  - ⟶ Content uniformity
- Cleaning validations
- Impurity identification by LC-MS/MS and GC-MS/MS
- Dissolution profiling

- Stability studies for drug products as per ICH
- Guidelines
  - → Intermediate stability
  - → Accelerated stability
- Stability studies for drug products as per ICH guidelines
- Method development and validation for heavy metals by ICP MS, ICP OES and AAS
- Method development and validation for residual genotoxic impurities by GC MSMS and LC MSMS

2. EXTRACTABLE AND LEACHABLE STUDIES

Extractable and Leachable Studies on Primary, Secondary and Tertiary Packaging Components, including Gum and Ink Migration Studies for:

- Ophthalmic Solutions
- Inhalation of aerosols and sprays
- Injections and injectable suspensions
- Inhalation Powders and Solutions
- Sterile Powders and Powders for Injection
- Transdermal Ointments and Patches
- Topical Powders, Solutions and Suspensions
- Topical and Lingual Aerosols
- Oral Powders, Solutions and Suspensions
- Oral Tablets and Oral Hard and Soft Gelatin Capsules

3. CHEMICAL TESTING

- Excipients
- Raw materials
- Intermediates
- Finished Formulations

4.CONTAMINANT TESTING

- Elemental impurity analysis by ICP-MS, ICP-OES and AAS as per ICH Q3D
- Analysis of Genotoxic Impurities by GC-MS-MS and LC-MS-MS
- Analysis of Nitrosamine Impurities by GC-MS-MS and LC-MS-MS
- Residual Solvents and Organic Volatile Impurities
- Residual Ethylene Oxide, Ethylene Glycol and Ethylene Chlorohydrin
- Quality testing of compressed air and nitrogen
- Water Testing: Raw, Processed, Drinking and Effluents

5.MICROBIOLOGY

- Microbial Assay Method Validations
- Microbiological tests as per the Harmonized Protocol (USP)
- Sterility Testing
- In vitro testing for bacterial endotoxins by the LAL
- Test or Gel-Clot method
- Preservative efficacy and antimicrobial effectiveness testing
- Total aerobic microbial count (plate count and fungal count)
- Tests for microorganisms like E. coli, Salmonella,
- Pseudomonas aeruginosa, Staphylococcus aureus and Clostridium perfringens, etc.
- Multivitamin assays and antibiotic assays
- Lactobacillus spore count
- Hygiene/Clean Room Audit

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 PRODUCT ANALYSIS AS PER AYUSH