

## Analysis with Integrity, Involvement, Ingenuity

### Equipments:

- LC-MS/MS
- GC- MS/MS
- ICP-MS
- Ion Chromatograph with Conductivity and Pulsed Amperometric Detector
- HPLCs with UV, PDA, Fluorescence and RI detectors
- HPLC with CAD Detector
- GCs with FID and TCD with HeadSpace Sampler
- Particle Size Analyser (Malvern Master sizer 3000)
- Specific Surface Area Analyzer
- Capillary Electrophoresis
- X-Ray Diffractometer
- Microwave Digester
- Nitrogen Evaporator
- UV Visible Spectrometer
- FTIR with ATR
- Soxhlet Extraction System
- Polarimeter
- Dissolution Apparatus
- Stability and Photo Stability Chambers
- Osmometer
- KF Coulometer with Thermoprep
- Shaking water bath



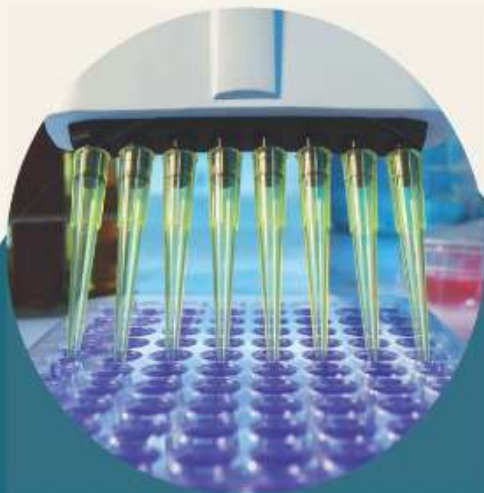
### **Energon Labs Private Limited**

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## Knowledge Driven Analysis



## **E**Nergon Labs

**An extension to your own laboratory**

## About Energon Labs

Energon Labs is a state-of-the-art Contract Analytical Services laboratory in Hyderabad, India, offering analytical services & solutions to Pharmaceutical, Medical Devices, Cosmetics and Nutraceutical industries with Integrity, Involvement and Ingenuity.

Energon Labs provide services in compliance to 21CFR Parts 210 and 211 (USFDA), Schedule LI of Indian Drugs and Cosmetics Act, PICS Guidelines, ISO 17025:2017, ISO 9001:2015, ICH Q10 and WHO GPPQCL.



## Why Energon Labs?

- We are an extension to your own laboratory
- Experience, Excellence and Expertise
- Prompt, Reliable and Accurate Services
- Quality built into every aspect of service
- Guaranteed Data Integrity and Data Security
- Less Turn-Around-Time
- Customized Analytical Solutions
- ISO: 17025:2017 Accredited Laboratory
- FDA FEI No. 3016445311
- Prompt response to post-service queries



## Quality Management System:

- An integrated QMS complying to Global regulatory & accreditation standards
- 21 CFR Part 11 compliance with complete audit trails
- Seamless and dynamic data archiving for complete data security
- LIMS for process and document control
- Total compliance to ALCOA+



## Range of Services:

- **Analytical Method Development:** Method development for - Identification, Assay, Related substances, Elemental impurities, carcinogenic impurities, Dissolution studies, Residual solvents, Particle size distribution etc.
- **Analytical Method Validation as per ICH Q2(R1):** Typical validation characteristics include Accuracy, Precision (Repeatability and Intermediate Precision), Robustness, Specificity, LOD, LOQ, Linearity and Range.
- **Wide Range of LC detectors:** Analytical development and testing on special Liquid chromatography detectors like Charged Aerosol Detector (CAD), Pulsed Amperometric detector, Conductivity detector, Refractive Index detector, Fluorescence detectors.
- **Carcinogenic Nitrosamine Impurities:** Energon has good expertise in developing, validating, and testing methods for determination of nitrosamines in pharmaceuticals.
- **Extractables And Leachables Testing:** Energon Labs offers complete services in Extractables and Leachables testing in pharmaceuticals and medical devices as per USP<1663>, USP<1664>, ISO:10993 and PQRI Guidelines.
- **Elemental Impurities as per ICHQ3D:** Elemental impurities in drug substances and drug products as per ICH Q3D, USP<232>, using ICP-MS.
- **In-Vitro Binding Studies:** Kinetic binding study / equilibrium binding study to demonstrate bioequivalence during product development and to meet regulatory recommendations.
- **QC Release Testing:** Analysis of APIs, Formulations and Excipients as per various pharmacopoeias including tests such as fatty acid compositions, residual ethylene oxide & dioxane, assay of cellulose products viz Hypromellose, ethyl cellulose, ethylene glycol and diethylene glycol in macrogols.
- **Particle size distribution:** Particle size distribution in dry & wet dispersion on Malvern master sizer-3000 by a team with good knowledge on micromeritics.
- **Wet Chemistry:** Titrimetric analysis, Specific Optical Rotation, Osmolality/Osmolarity, water content by coulometer etc.

