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About Us

Energon labs is a customer focused Analytical Testing Laboratory that provides services to Pharmaceutical, Biopharmaceutical, Medical Devices & Packaging Industries. ENergon Labs is a cGMP compliant, USFDA inspected, ISO 9001:2015 & ISO17025:2017 certified analytical testing laboratory located in Hyderabad, India.

Our Goal is to enhance patient health by providing High Quality & Cost-Effective Analytical Solutions.

Founded with a vision to be "An Extension to your own Laboratory", we deliver reliable analytical services in a timely manner with focus on Quality and Compliance. Our services are tailored to meet diverse client needs with a focus on Integrity, Involvement and Intelligence. You can rely on our experts and meticulous processes to consistently deliver data of exceptional quality that is precisely aligned to your specifications. We offer a dedicated project manager and technical expert, who will work closely with you to deliver projects on time.

Our Services :

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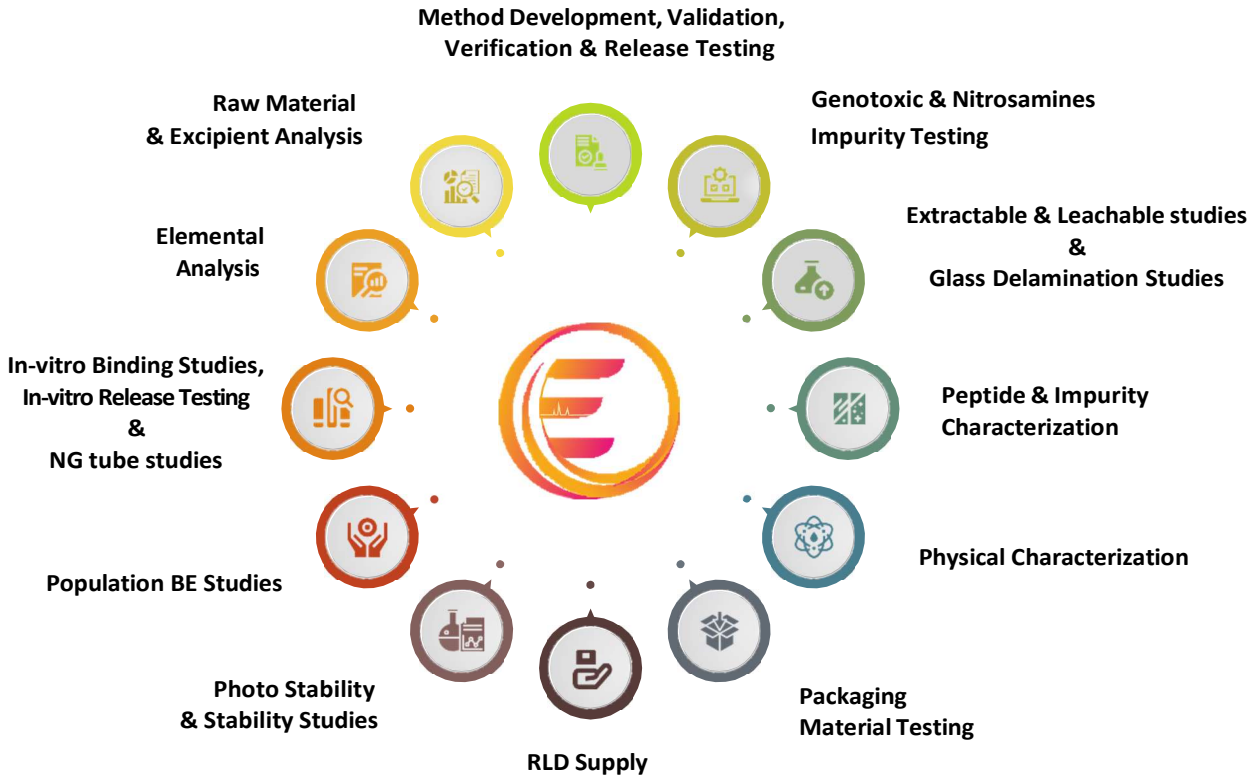

Method Development, Validation, Verification & Release Testing

Energon Labs can develop and validate methods for raw materials, excipients, drug substance and drug products.

With our diverse experience and research background we work with you to develop and validate a method to meet your specific requirements. Method development and validations are done compliance to compendial and regulatory requirements as per ICH Q2 (R2) guideline "Validation of Analytical Procedures: Text and Methodology" and USFDA guidelines. For compendial products we can support method verification as per USP <1226>, EP, and JP.

Energon Labs can draft and execute method transfer protocol/ programme as per WHO 961, Annex 7. All incoming methods will be thoroughly checked for performance characteristics through partial validation, lab-to-lab co-validation and comparative testing to generate a comprehensive documentation (plan, protocol and report).

- Specificity
- Forced degradation
- Precision/Repeatability
- Intermediate precision
- Accuracy
- Limit of Detection & Quantitation
- Linearity
- Range
- Robustness

Elemental Analysis:

Drug substance/products may contain trace amounts of elemental impurities that could be harmful, even at low concentrations. We test heavy metal or elemental impurity residues to ensure compliance with current regulatory requirements. Energon Labs offers highly sensitive ICP-MS testing services in line with ICH Q3D Guideline for Elemental Impurities. We test a variety of sample types and matrices for trace elements, including organic and inorganic materials, as well as aqueous and non-aqueous substances. We conduct analyses of over 24 elements, both metallic and non-metallic, as listed in ICH/EP/USP, with permitted daily exposures (PDEs) ranging from low parts per trillion (ppt) to high parts per million (ppm). Our mass spectrometry instrument features a unique collision cell that removes polyatomic interferences, enabling the analysis of complex matrices. Additionally, our high matrix introduction (HMI) equipment supports direct analysis of samples with high levels of dissolved solids.

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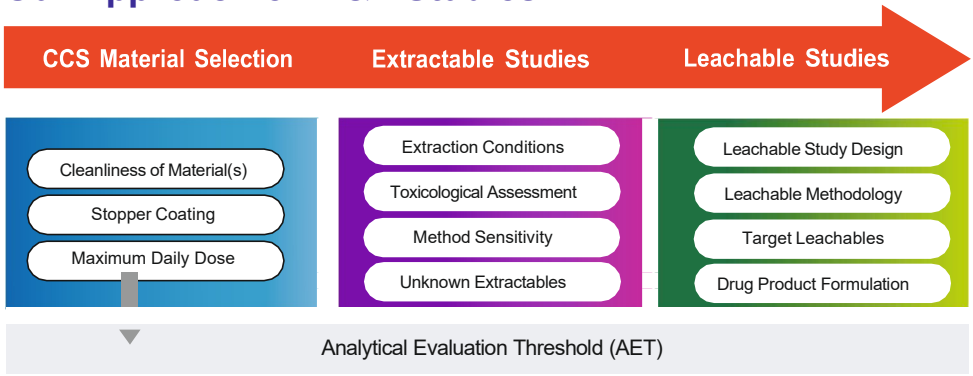
Extractables & Leachables

Energon Labs is a one Stop solution for testing Extractables in Container closure systems, Single-use manufacturing components, Ink migration, Glass delamination, Chemical characterization of Medical devices and Leachable studies in all dosage forms. We provide the assessment of extractable and leachable in bio/pharmaceutical products as an important step in drug product development and material qualification procedures.

Our team has relevant expertise to deliver extractable studies for wide range of articles including:

- Vials, Stoppers
- Pre-filled syringes
- COC, COP Containers
- Polymer tubing
- Filters
- Plungers etc
- SS/alloy components
- Gaskets
- O-Rings
- LDPE/HDPE bags.
- Ophthalmic CCS
- Medical devices

Our Approach on E&L Studies :



Integrated Solutions for E&L Challenges:

Large Volume Parenteral:

- Poorly defined MDD's
- Very low AET and Ultra-trace level method sensitivity
- Increased chance of unknowns and requirement of TOX assessment

Topical/Ointments/Creams :

- Complex Formulation/Matrix Effect
- Extractable study design for CCS
- Reachable strategy/Methodology

Metered Dose Inhalers (MDIS):

- Exhaustive extraction studies
- Complex leachable profiles
- Implementation of a control strategy

Medical Devices:

- Chemical Characterization study design for complex Medical devices
- Exaggerated / exhaustive extraction studies
- Cost-impact on testing more number of device

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Genotoxic & Nitrosamines Impurity Testing

Genotoxic Impurities are chemicals that can harm by causing damage to DNA. Regulatory agencies worldwide require thorough testing for these impurities. We can help you ensure compliance to safeguard consumer health.

Our process involves the comprehensive development, validation, and analysis of genotoxic impurities, meticulously assessing them against allowable maximum daily exposure targets.

We do testing according to ICH M7 (R1), USFDA, EMA and customer requirements for Identification and quantification.

Nitrosamines

Nitrosamines may increase the risk of cancer if people are exposed to them above acceptable levels and over long periods of time. Nitrosamine impurity testing is crucial in order to remain in compliance with health organizations. Nitrosamines can become part of pharmaceutical product during various stages of manufacturing. A vigorous test method is necessary to detect nitrosamines. Our expertise and capabilities can make sure your products do not exceed the daily intake limits.

Our expertise in dealing with method development and validation of Nitrosamine / NDSRI impurities with a focus to resolve key method optimization challenges and ensure precise & reliable results. With advanced hyphenated mass spec instruments, we develop methods for comprehensive screening and quantification of nitrosamines with sensitivities reaching up to sub ppb levels. Energon Labs can also develop methods for new nitrosamine impurities identified by the FDA. We stay up-to-date with the latest industry standards and technology advancements in N-nitrosamine impurity analysis.

Peptide Services

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Peptide Characterization:

Characterizing peptides presents complex challenges in establishing pharmaceutical equivalence between generic and innovator products, particularly due to inherent variations in peptide structure and manufacturing processes. Energon addresses these challenges by leveraging advanced analytical and bioanalytical techniques, along with the expertise of highly skilled team, to ensure product consistency and to mitigate lot-to-lot variability. Energon provides comprehensive support for ANDA submissions and streamline the product commercialization process, ensuring that peptide drug products comply with the highest standards of regulatory requirements, quality assurance, and bioequivalence.

Key Peptide Services:

- Molecular weight analysis by HRMS
- Amino acid sequencing by HRMS
- Peptide mass finger printing by HPLC/UHPLC
- Related substances by HPLC/HRMS
- Process related impurities by HPLC/Ion chromatography
- HMW Impurities/Oligomers/Aggregates by SEC-HPLC UV

Key Oligonucleotide Services:

- Purity/Impurity analysis by HRMS
- Purity/Impurity by Ion Exchange, RP-HPLC and CE
- Fourier transform infrared spectroscopy (FTIR)
- Residual Solvents by GC
- Elemental analysis by ICP/MS

Peptide Impurities:

Possible impurities are formed during the synthetic process due to Deletion sequences, Incomplete deprotection sequences, Sequence with amino acid modifications, Cleaved sequences and Amino- acid racemization.

- We can help you in characterizing and synthesis of impurities

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In- Vitro Binding Studies

The BE approach is not applicable for Locally Acting Gastro Intestinal Drugs since they are not intended to be absorbed into the systemic circulation and thus, drug concentration needs to be estimated at the local GI tract site. These drugs dissociate in the acid environment of the upper GI tract to release ionic drug species that bind to dietary phosphate or bile acids to form an insoluble complex that is eliminated via feces.

In-vitro studies are not a mere Analytical comparison between the test and reference. These studies are considered as substitute to clinical trial. USFDA has developed product specific guidelines for In-vitro BE studies i.e to compare the extent and rate of binding affinity between Test and Reference formulations where Assay to be performed with minimum 12 replicates at various pH conditions. It also includes equilibrium binding study with or without acid pretreatment and measurements of pH at different time points.

Drug products Expertise:

1. Sevelamer Tablet and Sevelamer Suspension
2. Colestipol Tablets
3. Sucralfate Tablets and Suspension
4. Cholestyramine Tablets and Suspension
5. Lanthanum carbonate Tablets
6. Calcium acetate Tablets

NG Tube Studies

We specialize in NG/G tube studies designed to evaluate drug delivery and bioequivalence for patients who cannot take medications via conventional oral routes. Our experienced team ensures all studies are conducted in full compliance with regulatory requirements, providing accurate and reliable data. We provide tailored study designs, including comparative recovery testing, sedimentation volume testing, and particle size distribution analysis, to optimize drug formulations for NG/G tube administration. By documenting patient-specific activities using DSLR technology, we ensure precise and accurate assessments of drug behavior. Energon is dedicated to delivering timely, high-quality results, to improve patient care and to meet regulatory standards for NG/G tube drug products.

Drug products Expertise:

1.Ruxolitinib Phosphate
2.Ticagrelor
3.Lenvatinib
4.Trofinetide
5.Lansoprazole DR

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Unlock Precision with Advanced XRD Services

At the forefront of analytical excellence, our lab offers comprehensive X-Ray Diffraction (XRD) capabilities powered by the Bruker D8 Advance davinci. Whether developing APIs or innovating with formulations, we bring precision, reliability, and regulatory alignment to your research.

Multi-Mode Flexibility for Diverse Needs

Our instrument supports:
Reflection Mode: Ideal for bulk analysis of solids.
Transmission Mode: Perfect for thin films and powdered samples.
Capillary Mode: Tailored for minute quantities and challenging matrices.

With these versatile modes, we ensure customized solutions that meet client specific project requirements.

Comprehensive Physical Characterization

For Active Pharmaceutical Ingredients (APIs):
- Identification and Quantification of crystal phase for quality assurance.
- Crystallinity & Amorphous Content Analysis to ensure product stability.
- Stress Testing to evaluate response to environmental or manufacturing conditions.

For Formulations:
We provide extensive testing for tablets, capsules, topicals (ointments, creams, gels), oral suspensions, granules, Inhalations and parenterals.

Our expertise includes:
Content Uniformity Analysis: To Ensure the consistent distribution of active pharmaceutical ingredients (APIs) in your formulations.
Identification of Polymorphic Forms: To ensure formulation consistency.
Quantification: To Deliver precise quantification of crystalline or amorphous content in APIs and formulations, meeting stringent pharmaceutical standards.
Comparative study: To Perform comprehensive analyses comparing RLD with test samples to establish equivalence in formulation and performance.

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Driving Excellence in Population Bioequivalence (PBE) for Particle Size Distribution (PSD)

Understanding the importance of **Population Bioequivalence (PBE)** in Particle Size Distribution (PSD) is essential for ensuring consistent quality and efficacy of pharmaceutical products. At the forefront of pharmaceutical innovation, PSD PBE studies have become a critical step, especially for complex formulations. Energon Labs harness advanced tools like Dynamic Light Scattering and Laser Diffraction for PSD analysis, ensuring FDA and EMA compliance with a skilled team and tailored solutions for modern pharmaceuticals.

PBE considers variability in sizes to ensure consistent drug performance across diverse populations. Parameters like **D50, D10, D90,** and **Span** are pivotal in analyzing PSD, and newer metrics like **Z-average** and **PDI** are evolving into critical benchmarks. **Regulatory bodies** like the FDA emphasize PSD PBE, especially for injectables and inhalables. From injectable biologics to inhalation therapies, PSD PBE ensures precision and safety, reducing risks of batch variability and therapeutic inefficacy. It's a testament to the power of science in improving lives.

Metrics Defined:

D50: Median particle size.
D10/D90: Represent smaller and larger particles in distribution.
Span: Quantifies distribution width.

Z-average and PDI (Polydispersity Index) offer advanced insight into particle uniformity. **PDI < 0.1** suggests a highly uniform sample.

Critical Applications:

- **Injectable Products:** Ensures therapeutic consistency in iron injectable, biologics and small-molecule injectables.
- **Ophthalmic Formulations:** Enhances efficacy in emulsions, suspensions, and other ocular delivery systems by maintaining uniform particle size.
- **Inhalation Therapies:** Optimizes aerosol performance and ensures proper deposition in the respiratory tract for dry powder inhalers and nebulized formulations.
- **Topical and Transdermal Products:** Improves spreadability, absorption, and therapeutic outcomes in creams, gels, and patches.
- **Oral Suspensions and Solutions:** Ensures uniformity in dosage and bioavailability for paediatric and geriatric formulations.
- **Parenteral Nutrition:** Maintains stability and efficacy in lipid emulsions and amino acid solutions.
- **Controlled and Targeted Release Systems:** Supports consistency in sustained, extended, or delayed-release tablets and capsules by ensuring proper drug release profiles.

Key Equipments

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Name of the Instrument	Instrument Make and Model	Quantity
IVRT	Logan - Automated - FDC-6TA	1
LC-MS Q-TOF	Agilent - 6545 XT & Revident Q-TOF	2
LC-MS Triple Quad	Sciex - 6500	1
LC-MS Triple Quad	Agilent - 6470	1
LC-MS Triple Quad	Shimadzu - 8060NX & 8060RX	2
GC-MS Triple Quad	Agilent -70108, 7010C & 7010 D	3
ICP-MS	Perkin Elmer Nexion 1000 and Agilent-7850	2
Ion Chromatography	Thermo Dionex - 5000 Plus	1
HPLC	Agilent -1260 infinity II	7
HPLC	Thermo scientific PDA with Corona CAD	1
GC-HS	Agilent -7697A	3
XRD	Bruker D8 advanced	1
Particle Sizer	Malvern - 3000	1
DSC	Perkin Elmer - 4000	1
SEM	Hitachi Bench Top	1
TOC	Shimadzu L Series	1
Coulometer	Metrohm 851Titrando	2
Capillary Electrophoresis	Agilent-7100	1
UV/Vis Spectrophotometer	Perkin Elmer Lambda 365	1
FT-IR/AT-IR	Perkin Elmer Spectrum two	1
Stability chamber	Nihar	4
Dissolution	Lab India DS - 14000	1

Accreditations:

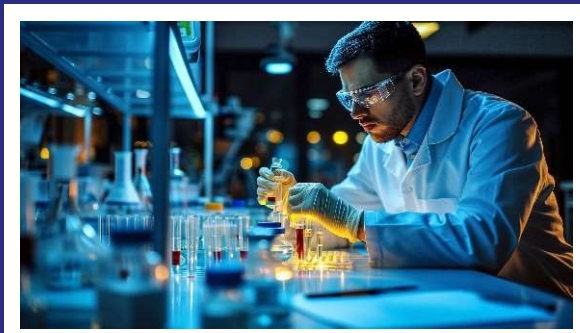
USFDA Approved

WHO-Geneva Pre-Qualification Completed

NABL Accredited (ISO 17025)

DCGI Approved

ISO 9001 Certified



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