ENergon Labs

An extension to your own laboratory

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.

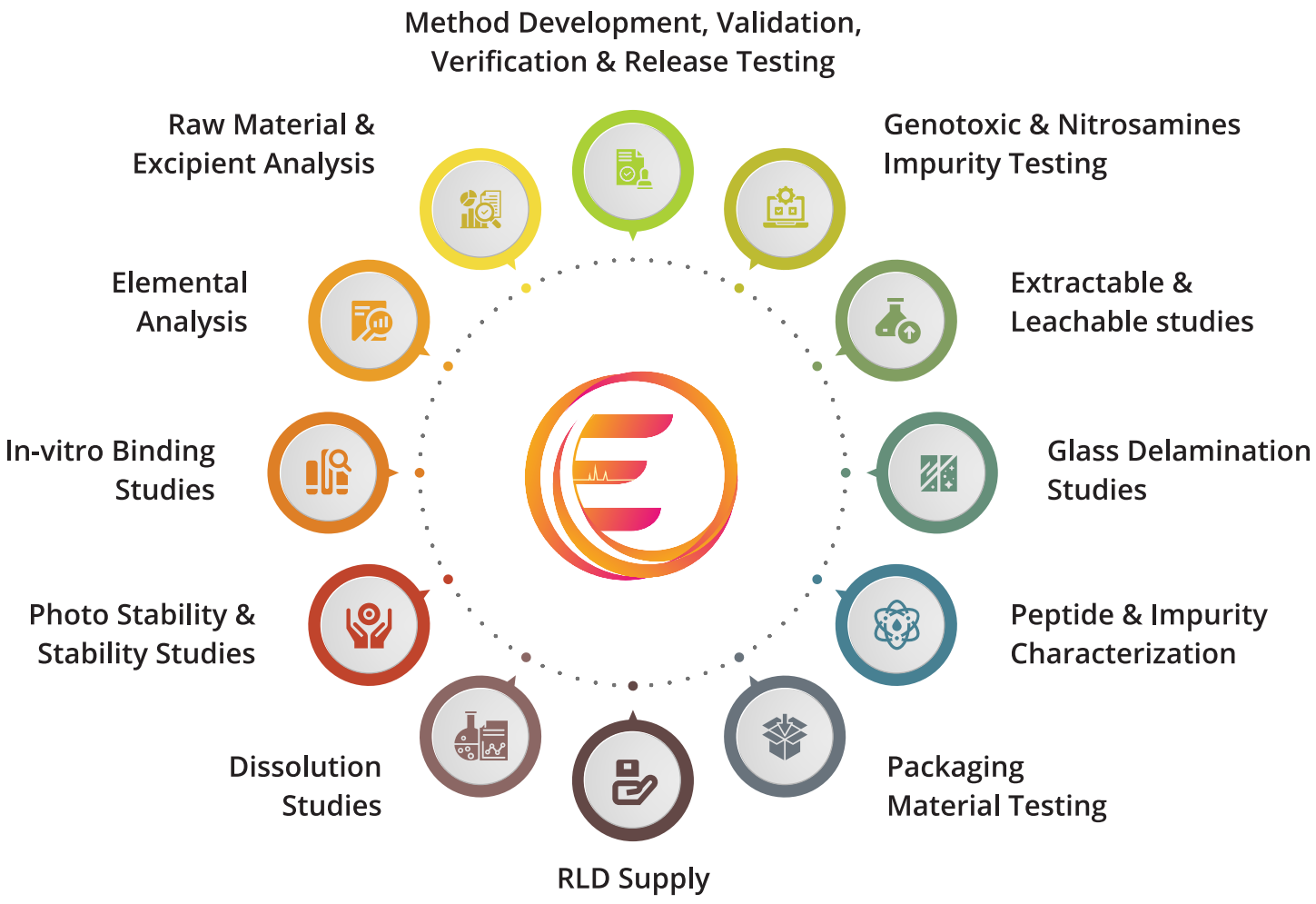
Our Goal is to enhance patient health by providing High Quality & Cost-Effective Analytical Solutions.

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

Provides comprehensive suite of analytical testing services for small and large molecules



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).

Method Validation Parameters:

- 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.

Extractables & Leachables

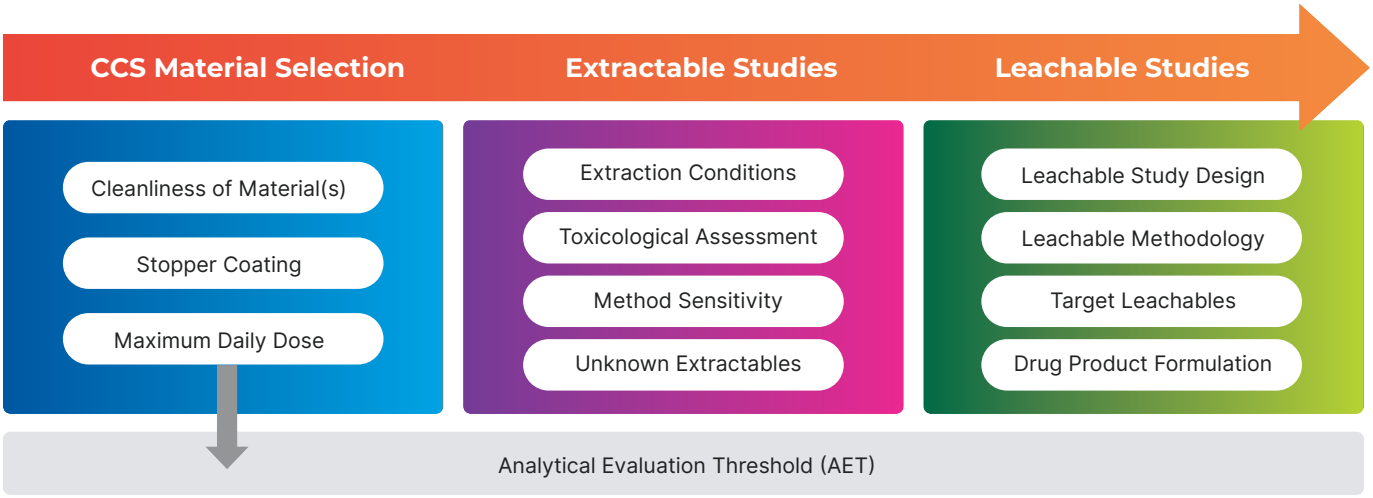
Energon Labs is a one Stop solution for testing Extractables in Container closure systems, Single-use manufacturing components, Ink migration, Glass delamination, Chemical characterization of Medical devices and Leachable studies in all dosage forms.

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
- LDPE / HDPE bags
- Ophthalmic CCS
- Medical devices
- SS / alloy components
- Gaskets
- O-Rings
- Polymer tubing
- Filters
- Plungers etc.

Our Approach



Integrated Solutions for E&L Challenges:

Large Volume Parenteral:	Topical / Ointments / Creams:	Metered Dose Inhalers (MDIs):	Medical Devices:
• Poorly defined MDD's • Very low AET and Ultra-trace level method sensitivity • Increased chance of unknowns and requirement of TOX assessment	• Complex Formulation / Matrix Effect • Extractable study design for CCS • Leachable strategy / Methodology	• Exhaustive extraction studies • Complex leachable profiles • Implementation of a control strategy	• Chemical Characterization study design for complex Medical devices • Exaggerated / exhaustive extraction studies • Cost – impact on testing more number of device

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.

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Peptide Services

Peptide Characterization:
Effective Characterization of peptide therapeutics at each step of manufacturing is necessary to minimize lot-to-lot variation in product quality. Ensuring the quality and equivalence between generic and brand name peptide drug products raises a number of challenges and those challenges differ according to the type of peptide drug. To prove the pharmaceutical equivalence of such synthetic peptides with the innovator drugs (Synthetic or rDNA origin), it is required to have a thorough understanding of advanced analytical and bioanalytical tools.

At Energon, we use scientific excellency of experienced team and hyphenated analytical tools to Characterize the product. We believe to be "An extension of your own laboratory", help you in successful ANDA submission and product commercialization.

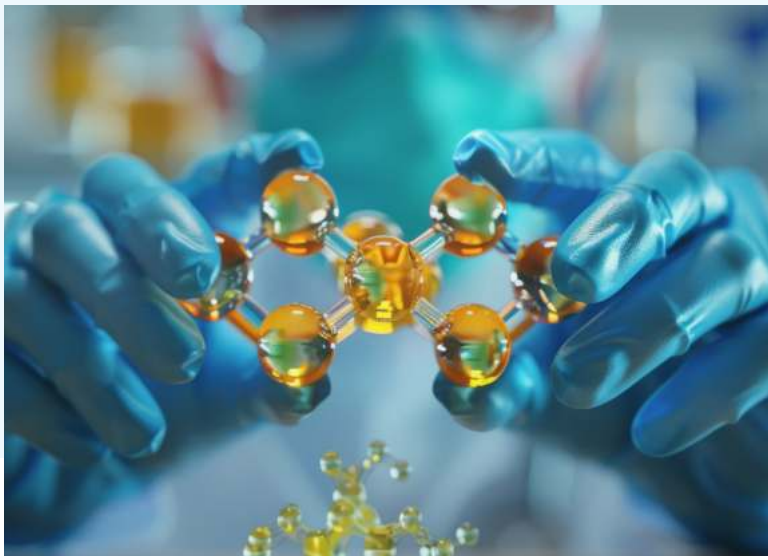
Key Peptide Services:
- Molecular weight analysis by HRMS
- Amino acid sequencing by HRMS
- Peptide mass finger printing by HPLC/ UHPLC
- Related substances by HPLC/HRMS
- Process related impurities by HPLC/Ion chromatography
- HMW Impurities/Oligomers/Aggregates by SEC-HPLC UV

Peptide & Starting material (SMs) Synthesis:
We make AAD's with utmost quality at an affordable cost that can be used as SMs for your peptide API. Having sound experience with AAD's and other starting material, we also provides quality API with highest possible purity.

Peptide Impurities:
Possible impurities during the synthetic process of a therapeutic peptide include Deletion sequences, Incomplete deprotection sequences, Sequence with amino acid modifications, Cleaved sequences and Amino- acid racemization.

Some impurities may also arise due to:
- Degradation mechanisms
- Purification methods or SPPS
- Side chain reactions of amino acids
- Excipient interactions

Well characterized high-quality impurity standards of synthetic peptides are utmost important to judge the quality of the product. At Energon, we can help you with synthesis of any impurities with greater purities.



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.

The flow of study:
1. Development trial
2. Validation of method for estimation of binding capacity on the lines of Bio analytical Method Validation guidelines
3. Pilot trial
4. Pivotal Study with first Kinetic binding followed by Equilibrium binding

Drug products Expertise:
1. Colesevelam Tablets and Colesevelam Suspension
2. Sevelamer Tablet and Sevelamer Suspension
3. Colestipol Tablets
4. Sucralfate Tablets and Suspension
5. Sevelamer Tablets and Suspension
6. Cholestyramine Tablets and Suspension
7. Lanthanum carbonate Tablets
8. Calcium acetate Tablets

Stability Testing & Storage

Energon Labs can support our client for execution of stability studies through well designed stability protocols, coordination for stability programme, timely pull We provide stability testing and storage services to the pharmaceutical industry.

Our facility conducts ICH stability studies using methods supplied by clients, compendial methods, or internally validated procedures. We test a wide range of drug formulations, including sterile injectables, tablets, capsules, non-sterile liquids, transdermal products, aerosols, and medical device combination products.

Our services cover both long and short-term (accelerated) stability programs, as well as photostability studies for both R&D and commercial products. Our stability storage chambers are meticulously mapped and continuously monitored by a validated system.

Stability Testing Services

- Formulation Development and Optimization Stability
- Real -Time Stability
- Accelerated Stability
- Freeze thaw Study
- Photo stability testing
- Commercial batch stability studies
- R&D batch exploratory stability studies

Storage & Conditions

Condition	Temperature & Relative Humidity
ICH Accelerated	40^0 C/75% RH
ICH intermediate	30^0 C/65% RH
ICH Long Term	25^0 C/60% RH
ICH Option ll	Photo Stability
ICH Refrigerated	5^0 C

*Other Conditions Available upon request

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Accreditations & Approvals

USDFA Inspected

WHO-Geneva Prequalification completed

NABL Accredited (ISO 17025)

DCGI Approved

ISO 9001 Certified

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