

EUTECH SCIENTIFIC SERVICES, INC

The Pure Power of Focused Research

*SERVICES
CATALOG*

Let Us Solve Your Challenges

EuTech Scientific Services is a Contract Research Company focusing on the development of new analytical methods and utilization of existing methods for the pharmaceutical, medical device, food and nutraceutical industries. We work with you hand in hand to achieve your goals.

We have been serving the industrial and academic scientific community since 1994. We are a knowledge-based company, having the experience helping our clients to achieve their goal by interacting with them during the entire span of their project. Our commitment is to provide the highest quality services to our customers

Industries We Serve:

Pharmaceutical

Medical devices

Nutraceutical

Consumables

Cosmetics

Scientific Instruments / Laboratory Consumables

Analytical Services:

Method Developmental and Validation

Extractable and Leachable

Impurity Profiling and Identification

Physicochemical Testing

Residue Analysis

Heparin/ LMWH

Cannabis

Litigation support

PHARMACEUTICAL

EuTech Scientific Services focuses on solving difficult problems for the pharmaceutical industry. Our knowledgeable and skilled staff will work hand-in hand with you and will become an extension of your own laboratory. EuTech provides the best quality analytical data with an excellent turnaround time. We have established a strict quality assurance department which routinely audits the facility for GLP/cGMP compliance. Our lab is DEA scheduled I to V.

Our services include:

1. Extractables and leachables
 - a. USP 660, 661, 671, 381
 - b. Heavy metals USP 232, 233
 - c. Containers closure testing
 - d. In process materials
 - e. Medical devices
 - f. Injectable
 - g. Ophthalmic
 - h. Single Use Systems
2. Separation and Identification
 - a. Impurities
 - b. Metabolites
 - c. Degradation products
 - d. Unknown compounds
 - e. Chiral compounds
 - f. Residual solvents
 - g. Amino Acids
3. Method developmental and Validation
 - a. Separation methods using GC/HPLC
 - b. Other analytical procedures
 - c. Transfer protocols

4. Heparin/LMWH
 - a. Molecular weight
 - b. Potency “anti IIa/ Xa”
 - c. Fragment mapping/chain mapping
 - d. Identification
 - e. Sulfate/ Carboxylate ratio
 - f. Limit of Galactosamine in Total Hexosamine
5. Miscellaneous
 - a. Raw material characterization
 - b. Monograph testing
 - c. Formulation compatibility
 - d. Release testing
 - e. Product integrity
 - f. Development of customized protocols
 - g. ELISA

Medical Devices

EuTech Scientific services serve medical device companies by aiding in the development of their quality assurance program and in their research and development. We offer the highest quality comprehensive service. EuTech is fully compliant with GLP/GMP regulations. We accept Research and Method development contracts from Medical Device companies for products/methods. We perform research project to improve existing products or introduce a complete new line of products. We perform research in changing/ revising existing methods to improve the process, reduce costs, and minimize procedure time.

Contact us for the following services:

1. Analysis
 - a. Extractable and Leachable identification
 - b. Residue Quantification
 - c. Binding Assays
 - d. Containers and Closures Testing
2. Physico-Chemical testing
 - a. Pore Size distribution and Bubble point
 - b. Gas and Liquid permeability
 - c. Material Characterization
 - d. Compressibility
 - e. Resilience
 - f. Filter integrity
 - g. Water Uptake
 - h. Durometer
 - i. Spectrophotometry
3. Stability
 - a. Shelf Life
 - b. Accelerated aging
 - c. Controlled Temperature and Humidity
4. Miscellaneous

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- a. Freeze Drying
- b. Milling

Nutraceuticals

Nutraceuticals enrich the nutrients present in food. The early detection of contaminants in Nutraceuticals is of utmost importance. The scientists at EuTech have extensive experience in this field. Our advanced instrumentation enables us to monitor nutraceutical for metal, reuses and other impurities. Products tested include a wide range of minerals, vitamins and dietary supplement. Our staff is familiar with non-routine testing and to possess the skills and resources to meet your needs. Methods are validated to current USP/ICH guidelines. EuTech can provide product development support and assist in existing products. EuTech can make sure that your Label claims are backed up by proper scientific testing.

Identification and Quantification available through:

1. GC
2. HPLC
3. GC-MS
4. LC-MS/MS
5. ICP-MS
6. Ion Chromatography
7. FTIR

Contact us for:

1. Method development and validation
2. Compendia testing<USP/NF/EP/JP
3. Stability Testing
4. Assay Testing
5. Physical testing
6. Impurity and degradation product monitoring
7. Development and validation of stability indicating assays

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Cosmetics

EuTech Scientific Services is a highly qualified laboratory for testing cosmetics. EuTech has helped companies with challenging issues in the cosmetics industries. We will test your new existing cosmetics for any harmful substances. Contact us for testing of soaps, lotions, aromatherapy, sunscreen, detergents, shampoos, etc. Our laboratories will ensure that your products are completely free from harmful contaminants so you can rest assured that the consumers are served with high quality safe products.

Contact us for following:

1. HPLC and GC analysis
2. Analysis of raw materials used in cosmetics as per relevant specification
3. Testing for active and other ingredients, preservatives, fragrances and contaminants.
4. Counterfeit products
5. Toxic substances
6. Residual Solvents
7. Stability studies
8. Characterization using GC-MS / LC-MS / ICP- MS
9. Phthalates
10. Predictive shelf life
11. Request more information how can EuTech can help you

Scientific Instruments and Laboratory Consumables

EuTech Scientific Services is a leader in the testing and analysis of laboratory consumable products. Our highly experience team has been providing analytical services for laboratory consumable manufacturers for over 10 years. Testing is conducted in our state-of-the-are facilities. Our knowledgeable and skilled staff is experts in the testing of laboratory consumables. We will work hand.in-hand with you to ensure that your products are the best quality on the market.

Contact us for the following services:

1. Vials
 - a. Absorption
 - b. Extractable/Leachable
 - c. Salinized Vials
 - d. Inserts
 - e. Auto sampler
 - f. Compatibility
 - g. Light Transmittance
 - h. Resin Analysis
2. Caps
 - a. Sealing/Resealing
 - b. Vial Compatibility
 - c. Leaching
3. Septa
 - a. Chemical Compatibility
 - b. Coring
 - c. Defects
 - d. Extractables (HPLC, LC-MS, GC, GC-MS)
 - e. Contaminants
 - f. Sealing/Resealing
 - g. Inert Port septum Bleed

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- h. Inert Port Septum
- i. Lifetime
- j. Durometer
- 4. Filters/membrane
 - a. Pore Size Analysis
 - b. Bubble Point
 - c. Extractables
 - d. Filter integrity
 - e. Absorption
 - f. Protein binding
 - g. Retain Volume
 - h. Zeta Potential
- 5. Other
 - a. Product Certification
 - b. Product Evaluation
 - c. Complete Analysis
 - d. Raw Material QC
 - e. Certification For GC- MS, LC- MS, ICP- MS , and GC Head Space

PHYSICOCHEMICAL TESTING

EuTech Scientific Services is a leading provider in physico-chemical testing. We have vast experience providing data for product development and pharmaceutical R&D support. We offer a full range of services at an affordable price and operate in accordance to the GLP requirements.

Contact us for the following:

1. Melting point
2. Boiling point
3. Viscosity
4. Flammability
5. Surface tension
6. Gas and liquid permeability
7. Water solubility
8. Gravity
9. Alkalinity
10. Ammonia
11. Biochemical Oxygen Demand
12. pH
13. Total Suspended Solids
14. Turbidity

Extractables and Leachables

The qualified team at EuTech Scientific Services possess years of experience with extractable and leachables services. The issue related to extractable and leachables has always been a great challenge in the food and pharmaceutical industries wherein safety becomes primary concern with the use of glass, plastic and rubber in a number of packaging materials. We develop the customized protocol for your product to meet FDA requirements based on guidelines from Packaging Quality Research Institute (PQRI), Bio-Process System Alliance (BPSA), Bio-Phorum Operational Group (BPOG), American Society of Testing Material (ASTM) and US Pharmacopeia (USP)

Our experienced team at EuTech Scientific Services will assist in every aspect of the project from the initial stages of planning to its execution.

1. The extractable study:

- a. Design and execution of the extractable study on critical components of the primary packaging, covering inorganic and organic extractable.
- b. Determination of the Analytical Evaluation Threshold (AET) from the Safety Concern Threshold (SCT)
- c. Use of a number of extraction methods, employing multiple analytical techniques, as no one analytical technique is capable of detecting all extractable substances
- d. Provision of a detailed technical report, containing full results and chromatograms
- e. Option for undertaking a literature based toxicological assessment of the detected extractable to identify target leachable.

2. Simulation Study

3. The leachable study:

- a. Development and validation of methods for the assessment of leachable in the drug product.
- b. Analysis of stability time point samples for leachable

4. Analytical Techniques

- a. Gas Chromatography Mass Spectrometry (GC-MS)
- b. Liquid Chromatography Mass Spectrometry (LC-MS/ MS)
- c. Non-Volatile Residue (NVR) and Fourier Transform Infrared (FT-IR) spectroscopy
- d. Inductively Coupled Plasma Optical Emission Spectrometry (ICP-MS)
- e. PH
- f. Conductivity
- g. Total Organic Carbon (TOC)
- h. USP 661 and USP 671

5. Custom Program

- a. Risk Assessment and Study Design
- b. Extractable study
- c. Data Assessment
- d. Leachable Method
- e. Leachable Validation
- f. Leachable Shelf Life

6. Single Use Systems

- a. An assessment of Extractable and Leachable is important for patient safety and to assess any potential impact on the process and product.
 - i. SUS components include filters, bags, tubing, connectors, gaskets, and valves
 - ii. Factors that affect that assessment include nature of the extractable species, process fluid, contact time, contact temperature, downstream processes.

7. Risk-based Approach to evaluating Extractable and leachable

- a. Safety Considerations
 - i. Toxicity, immunogenicity etc.
- b. Efficacy consideration
 - i. Leachable interacting with a product.
 - ii. Loss of activity

- iii. Leachable may induce development of neutralizing activity
- c. Quality Considerations
 - i. Impact on manufacturing process, product stability etc.

Litigation Services

EuTech Scientific Services will provide detailed testing and expert testimony in legal cases in our area of expertise. Our knowledgeable staff is ready to meet any challenge. Our reports are true to the roots, in an understandable format to all audiences. We adhere to GLP guidelines of FDA. All work is performed under strict confidentiality.

Contact us for the Following services:

1. Reviewing the technical issues in a case
2. Suggested Testing/ Retesting
3. Support Method development
4. Generation of Technical Data
5. Evaluation and interpretation of Data
6. Relevant literature Searches
7. Sworn Testimony and Trial Attendance
8. Help Intellectual Property/patient Disputes
9. Product Liability Support
10. Product failure investigation
11. Personal injury due to chemical exposure
12. Technical document preparation

Instrumentation

- HPLC System {with UV/VIS, Diode array, Evaporative light Scattering (ELSD), Fluorescence and Refractive Index Detectors }
- GC System (with Head Space analysis)
- Gel Permeation chromatography system
- Ion Chromatography Conductivity and Pulsed Amperometric Detection
- GC- MS
- LC-MS/MS Systems
- ICP-MS
- FT-IR
- UV Spectrophotometers
- ELISA
- Gel Electrophoresis systems
- Capillary Flow Porometer
- Plastometer/durometer
- Freeze dryers
- Controlled condition Incubators/Enviro- chambers
- Powder mills
- Exhaust Hoods (Chemical and Class II Biological)

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