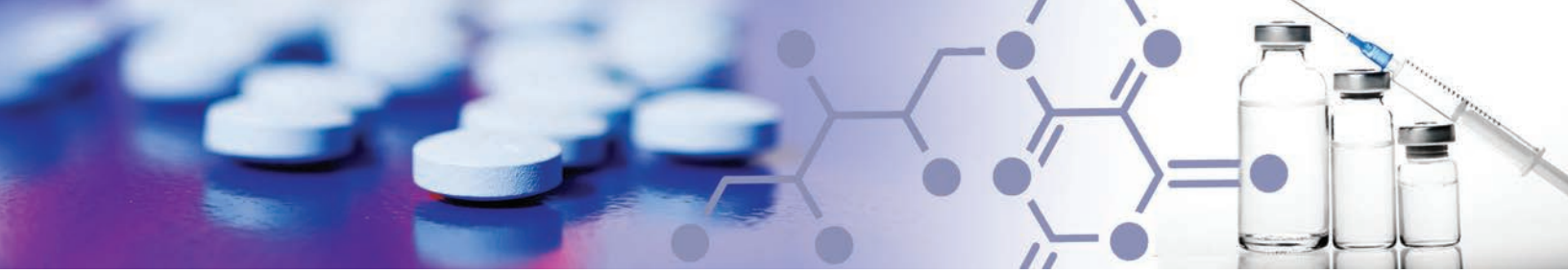
Your Ultimate Guide to...

Raw Materials Testing Support

No bio/pharmaceutical product can be manufactured without first establishing the identity, purity and quality of its starting materials to ensure the product is suitable for its intended use. When this critical step in the bio/pharmaceutical manufacturing process is performed successfully, costly production problems and delays can be avoided.

Why Choose Eurofins BioPharma Product Testing?

- We provide the most comprehensive raw materials testing package, including 24/7 online access to data and flexible service models such as Fee-For-Service and Full-Time Equivalent programs.
- Our extensive testing experience, coupled with expertise in scientific problem solving and compendial consultation, allows us to successfully meet your testing challenges and help you prevent costly production problems and delays.
- We are equipped to perform testing in accordance with current EP, USP/NF, BP, JP, ACS and FCC methodologies and monographs, in addition to any client-supplied or vendor-defined methods.
- We offer a one-stop-shop with over 800,000 ft^2 of laboratory space in North America, backed by 2,000 dedicated laboratory staff supporting Raw Materials Analytical Chemistry, Biochemistry, Cell Biology, Microbiology and Viral Safety testing services.
- We support more than 80 Platform Method Services for rapid implementation of GMP QC testing.



Dedicated Raw Material Capacity

4 US Labs | Over 500 Raw Materials Scientists

Lancaster, PA

Complete compendial/ non-compendial chemistry, biochemistry, cell-based and microbiology services

Portage, MI

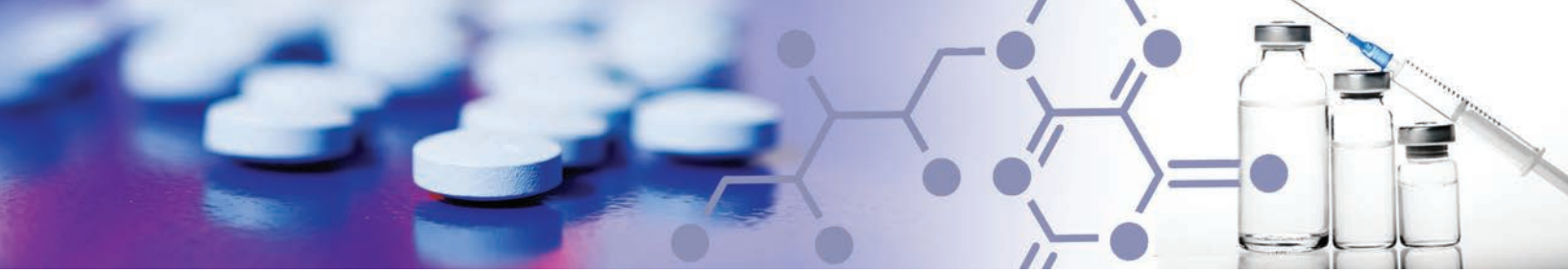
Compendial chemistry and microbiology services

Columbia, MO

Chemistry and biochemistry non-compendial services

Jacksonville, FL

Compendial raw material services



Comprehensive Raw Materials Testing Capabilities

Analytical Services

Compendial Analysis

Eurofins BioPharma Product Testing network of laboratories has the wide range of chemistry expertise and state-of-the-art instruments required to perform all types of raw materials testing, including qualification of compendial methods.

Whether you are looking for assistance in the release of your raw materials for production purposes or in the qualification of your vendors, we can help keep your project on track. We are equipped to perform testing in accordance with current EP, USP/NF, BP, JP, ACS and FCC methodologies and monographs.

Containers Testing

A critical step in understanding the biological safety and suitability of a container is the ability to characterize the materials and chemicals that have the potential to migrate through the container's system components, resulting in contamination or degradation of the drug product.

Eurofins BioPharma Product Testing network of laboratories performs testing on virtually all container types requiring evaluation, including plastic bottles, glass vials, stoppers and raw plastic (resin pellets, sheets, etc.).

Water Content Testing

Eurofins BioPharma Product Testing network of laboratories offers a comprehensive range of microbiology and chemistry capabilities in support of your facility monitoring and process validation projects—all performed in strict adherence to cGMP requirements. We have completed more than 200 facility validation projects for pharmaceutical manufacturers, biopharmaceutical companies, pilot plants, API manufacturers and tissue processors. Our experts are well versed in fulfilling validation needs with the flexibility to handle the unique specifications of any project.

Click the links to learn more about our testing services

Comprehensive Raw Materials Testing Capabilities

Non-Compendial Analysis

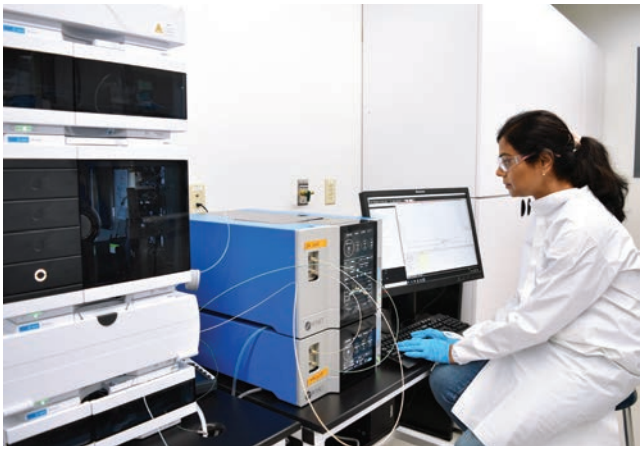
The quality and efficacy of materials used in bioprocesses are critical in pharmaceutical manufacturing. There are many factors that make testing particularly challenging, which become even more complicated when there is no compendia monograph to support your raw materials control strategy.

Eurofins BioPharma Product Testing brings over 30 years of experience in Raw Materials, culminating in the introduction of over 80 platform general analyses. These multi-material platform methods reduce the time taken to establishment methods for GMP use and provide the validation packages needed for all phases of manufacturing.

Characterization Testing

Characterization testing is used to gain an understanding of the physical and chemical properties of pharmaceutical materials.

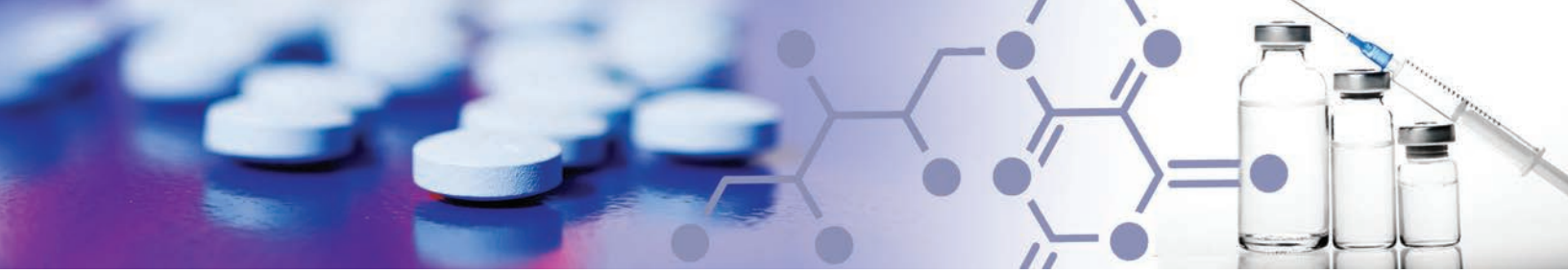
Eurofins BioPharma Product Testing network of laboratories provides cGMP compliant and non-GMP investigational characterization testing for pharmaceutical materials to support formulation, process development, quality control, GMP lot release testing, and investigational manufacturing troubleshooting. We have extensive experience with an array of product types from raw materials to active pharmaceutical ingredients and can accommodate virtually any product type.



Raw Materials Testing for Cell & Gene Therapies

Eurofins BioPharma Product Testing is well-versed in evaluating critical quality attributes (CQAs) of a diverse range of ancillary and raw materials, including monographed and non-monographed materials used in cell and gene therapy products. Using established GMP methods, platform techniques, and customized methods, Eurofins BioPharma Product Testing provides robust, flexible, and high throughput lot release testing for the fast-paced manufacturing of today's therapies.

Our dedicated Biologics Raw Materials testing team has vast experience in cell and gene therapy manufacturing from early clinical, through process validation, product optimization, and marketed release.



Comprehensive Raw Materials Testing Capabilities

Safety Services

Residual Solvents Testing

Pharmaceutical companies are increasingly demanding full residual solvent screening, with method validation, due to more complex formulations, complicated active ingredient structures, and high product safety requirements.

Eurofins BioPharma Product Testing's network of laboratories offers many testing options to satisfy each customer's needs. Testing options range from a residual solvent screen, which may evaluate classes of solvents, to a very specific method that was developed and validated specifically for the solvents of interest in a particular sample matrix.

Metals Testing

Eurofins BioPharma Product Testing offers an array of testing services for a variety of applications that contribute to product integrity, including drug substance and raw materials assays, cleaning validations, media screenings, extractable/leachable studies and final product assays.

Our expertise and instrumentation enable analysts to offer a wide range of assays according to pharmacopeias (USP, EP, BP, JP, etc.), including support for the launch of the harmonized approach to elemental impurities ICH Q3D, as well as other customer specifications. Capabilities are available using ICP-MS, ICP-OES, Flame AA, Graphite Furnace AA and Cold Vapor AA (mercury).

Microbial Limits Testing

Eurofins BioPharma Product Testing provides Microbial Limits testing that may be needed for some raw materials testing projects, enabling customers to streamline the analytical process by opting for microbial limit testing while their raw materials project progresses.

Our team, working in state-of-the-art controlled and HEPA filtered microbiology laboratory facilities, provides the scientific expertise necessary to complete Microbial Limits testing projects quickly and effectively.

Comprehensive Raw Materials Testing Capabilities

Sterile/Non-sterile Raw Materials and Component Testing

Eurofins BioPharma Product Testing's network of laboratories offers a comprehensive range of microbiology services with strict adherence to cGMP requirements in support of sterile and non-sterile product testing and facility monitoring for bio/pharmaceuticals, including raw materials, cell lines and unprocessed bulk testing. We offer both clean room and isolator technologies for sterility testing, enabling application of the most appropriate technology for your products.

With seamless project management, our laboratory becomes an extension of your own operations, producing additional capacity to complement your internal microbiology laboratories.

Mycoplasma Testing

Eurofins BioPharma Product Testing provides Mycoplasma Detection testing that may be needed for some raw materials used in process for biopharmaceuticals. We offer both compendially based testing methods as well as rapid methods that may be used in place of the compendial methods for raw material testing. All of our mycoplasma detection methods are harmonized across the USP, EP, JP, and PTC.

Adventitious Agents Testing

For all stages throughout the development, manufacturing and release of your biological product, Eurofins BioPharma Product Testing offers comprehensive, fully cGMP-compliant Viral Safety Services.