



BioPharma
Product Testing

A Global Reference in Laboratory Testing



Laboratory excellence to support your testing of
biocidal products, detergents and biopesticides



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GLP • ISO/IEC 17025 • GMP • FDA • ISO 9001 • ISO 22716 • ISO 13485



About Eurofins

Worldwide excellence in bio-analytical testing

With EUR 2.54 billion in annual revenues and over 30,000 employees in around 375 sites in 41 countries, Eurofins Scientific is a leading international group of laboratories providing a unique range of analytical testing services to the pharmaceutical, food, environmental and consumer products industries and to governments.

Comprehensive services and unmatched expertise

With its global network of state-of-the-art laboratories and operations across all continents, Eurofins is a worldwide leader in its field. The Group offers a portfolio of over 130,000 analytical methods for evaluating the safety, identity, composition, authenticity, origin, traceability and purity of biological substances and products. Through research and development and acquisitions, the Group draws on the latest developments in the field of biotechnology and analytical chemistry to offer its clients unique analytical solutions and the most comprehensive range of testing methods.

A commitment to provide top quality and customer service

The Eurofins Group is committed to provide the highest quality services, accurate results in time and expert advice by its highly qualified staff. The reliability and accuracy of its data help customers make adequate decisions on risks and meet their increasingly stringent quality and safety standards and the expanding demands of regulatory authorities around the world.

Permanent innovation and support by the market leader

Few testing laboratories can combine the level of expertise, technological leadership, attention to quality and customer service that have made Eurofins the global leader in many of the fields where it is active. Large investments in innovation, technology, IT and logistics and very large sample volumes ensure that customers enjoy high standards of quality at reasonable prices.

High standards and flexible solutions

Eurofins tests comply with the relevant standards of accreditations defined and monitored by national and international bodies. Customers are guaranteed a flexible and responsive service, whether this involves standard testing or tailored solutions for sophisticated tasks.

Benefits of a global “multi-specialist”

Many of Eurofins’ international customers have developed a very close and long-term relationship with the Company. They recognise Eurofins as highly competent “one-stop-shop provider” of testing services. Eurofins offers not only a broad portfolio but is also an expert in most areas of activity. The Group has at least one laboratory with internationally recognised expert status. Through excellent logistics and information technology, the Group can offer this expertise through all its laboratories, allowing Eurofins to be a “multi-specialist”.

“Eurofins analyses everything that impacts human health and safety”



Eurofins BioPharma Product Testing

Eurofins BioPharma Product Testing, part of Eurofins Group, is the largest network of harmonised bio/pharmaceutical GxP product testing laboratories worldwide accross multiple industries. Our laboratories offer a broad range of methodologies under GMP and GLP authorization, ISO 17025 accreditation and ISO 9000 certification. Analyses are performed according to European Pharmacopeia (EP), United States Pharmacopeia (USP) and Japanese Pharmacopeia (JP) as well as specific customer methods.

A strategic partner to support the biocidal, detergents and biopesticide industry worldwide

Eurofins BioPharma Product Testing Italy, is both GLP and ISO 17025 accredited to perform standard and customized efficacy tests on preservative and disinfectant products for all application areas.

Our service offerings are fully comprehensive and include physical-chemical, stability, toxicological and eco-toxicological studies on active substances and products.

Our core philosophy

Eurofins BioPharma Product Testing Italy, with over 40 years of cGMP/GLP compliance, provides a unique combination of expertise, state of-the-art technology and high standards of quality for testing services.

We offer a comprehensive range of GLP compliant laboratory services coupled with innovative scientific solutions that help you better manage your development process.

With over 220 highly qualified employees we are committed to provide first-class quality services and accurate results in time.

Our 8000 square meters facility located in Vimodrone, Milan, offers extensive analytical laboratory capacity and top level of instrument technology, allowing us to manage projects of any size and scope.

Why choose Eurofins BioPharma Product Testing Italy?

We are able to give you a one-stop solution for biocidal products, detergents and biopesticides testing according to BPR requirements. With a constant focus on regulatory compliance, we have developed a study group, to support our customers with technical expertise and Project Management, capable to satisfy requirements on new substances and products through the entire life cycle, from R&D to marketing. We are able to perform both harmonized and customized studies to meet Sponsor's specific requirements.

Our exceptional experience and broad portfolio of laboratory testing services means that Eurofins BioPharma Product Testing Italy is ideally qualified to offer advice to customers to help them understand and comply with the local regulations applied in different countries.

Clients can benefit from a consistent, reliable and fast service due to our expertise in scientific problem solving. The large volume of analyses carried out, wide experience and scale effects, enable us to offer top quality analytical services at a reasonable price. We can help our customers to manage their quality budget more effectively, and optimise analytical testing spend. This leads to reduced risk and increased profitability for our customers, and to an overall return on their investment.



Biocides testing

Biocides are active substances and preparations containing one or more active substances that combat harmful or unwanted organisms, and because of their properties and uses may pose a threat to human health, animals, and the environment.

The new EU BPR (EC Regulation 528/2012), which came into force in September 2013, concerns the placing on the market and use of biocidal products. The new regulatory scenario aims to improve the operation of the European market and to protect human health and the environment.

The focus of the Regulation is towards the products into which the substances are incorporated. All biocidal products require an authorisation before they can be placed on the market, and the active substances contained in that biocidal product must be previously approved.

The BPR includes a two-step authorisation process: any active substance used in a biocidal product should be approved at the European Union level, after which the product is authorised at the member state level. Authorisations can apply across member states through the use of mutual recognition. To avoid duplication of resource, administration of the BPR has been passed to the European Chemicals Agency (ECHA).

The BPR covers 22 biocidal product types, divided into four main groups:

Disinfectants (PT1 to PT5)

(Human hygiene biocidal products, private area and public health area disinfectants and other biocidal products, veterinary hygiene biocidal products, food and feed area disinfectants, drinking water disinfectants)

Preservatives (PT6 to PT13)

(In-can preservatives, film preservatives, wood preservatives, fibre, leather, rubber and polymerised materials preservatives, masonry preservatives, preservatives for liquid-cooling and processing systems, slimicides, metalworking-fluid preservatives)

Pest control products (PT14 to PT20)

(Rodenticides, avicides, molluscicides, piscicides, insecticides, acaricides and products to control other arthropods, repellents and attractants)

Other biocidal products (PT21 – PT22)

(Preservatives for food or feedstocks, antifouling products, embalming and taxidermist fluids, control of other vertebrates).

Testing of biocides according to the EU BPR (EC Regulation No 528/2012)

Under the terms of the new Regulation, a biocidal product should contain active substances with a more favourable environmental and human health profile. Companies must ensure that existing supply chains and biocidal product designs are in compliance with the new regulatory framework.

Whether you need to approve a new active substance or register your biocidal product according to EU BPR (EC Regulation 528/2012), Eurofins BioPharma Product Testing Italy provides industry-leading testing capabilities to meet regulatory obligations.

With an outstanding analytical expertise, highest standards of quality and state-of-the-art instrumentation, we offer the most complete laboratory testing services according to the principles of Good Laboratory Practice (GLP) and ISO 17025 as well as specific customer methods.



Full testing services offered to the biocidal industry

Physico-chemical properties

According to OECD, CIPAC, 440/2008EC methodology

Analytical chemistry

- Validation of analytical methods to identify and quantify active ingredients and impurities
- Technical equivalence studies
- 5-Batch analysis for active ingredients and impurities
- Residues studies

Stability studies (FAO, GIFAP, CIPAC, OPPTS Guidelines)

- Accelerated storage stability
- Low temperature stability
- Long term stability

In vitro toxicology

- Acute toxicity, local tolerance and sensitization tests

Aquatic and terrestrial ecotoxicology

- Fish, Daphnia magna, freshwater algae and cyanobacteria

Microbiology and efficacy testing

Preservative efficacy testing

Standard and customized test design

Quantitative suspension and carrier tests according to CEN standards

- Against gram positive and gram negative bacteria
- Against mycobacteria
- Against fungi (yeasts and molds)
- Against bacterial spores
- Against legionella

Efficacy studies for skin disinfectants (on volunteers)

- Hygienic handrub and handwash
- Pre-surgical hand disinfection

Efficacy studies against standard viruses

According to EN 14476, EN 14675, prEN 16777, EN 13610

Efficacy studies against specific viruses

Wide specific viruses portfolio

Efficacy studies for surface wipe disinfectants

According to EN 16615

Efficacy airborne studies

- Standard studies vs microorganisms and viruses: AFNOR NF T 72-281
- Customized studies: On the basis of Sponsor's device features
- Surface airborne disinfection for US: GLP customized protocols for EPA registration of fogging devices

Efficacy studies vs other targets

- Biofilm: Modified EN ISO/TS 15883-5, ASTM
- Insects and rodents (Subcontracted to partner laboratories)

Efficacy studies for US market

- ASTM and AOAC Standards: For EPA and FDA registration of antimicrobials

Testing on detergents and household products

Eurofins BioPharma Product Testing Italy provides testing, certification, and consulting on detergents and household products to manufacturers, distributors and retailers.

Our expertise encompasses a multitude of national and international specifications and regulations. Our main focus is the quality and safety of your products, ensuring that these characteristics are preserved through all product's life cycle, from R&D to marketing.

Performance test

We provide a wide panel of testing services for both the industrial and commercial markets. All-purpose cleaner, dishwashing, laundry and bathroom products are examples of products that can be tested according to most common international standards including IKW and A.I.S.E. protocols.

Suitable protocols are developed to support a specific claim. Product's compliance with Ecolabel and local environmental criteria is evaluated.

Human safety evaluation

Proper safety evaluation of detergents and household products is necessary for the correct classification of ingredients and formulations. In the context of the European regulatory framework, dealing with the complexity of REACH and CLP regulation, Eurofins BioPharma Product Testing Italy provides testing support and regulatory advice to ensure product tolerability and safety.

State-of-the-art *in vitro* laboratory is compliant with the latest developed protocols and guidelines to evaluate eye and skin irritation. Assessment of skin tolerability may also be performed on volunteers following the A.I.S.E. recommendations.



Environmental safety

Biodegradability tests are required to evaluate the environmental fate and behaviour of materials. Eco-toxicological tests are performed according to OECD and ISO standards. Data obtained provide the necessary information about compound's toxicity on representative organisms.

Microbiological analysis and physical-chemical characterization

Microbial contamination evaluation aims to ensure the safety of the product and rule-out the possibility of microbial spoilage. Absence of any relevant pathogen should also be tested for a complete assessment of microbiological safety.

The evaluation of the efficacy of the preservative system can be verified according to standard and customized protocols, which may also include in-house isolated microorganisms for a reproduction of in real life manufacturing environment and in-use conditions.

Biopesticides testing

Biopesticides are pesticides derived from natural materials as animals, plants, bacteria and certain minerals and whose main function is to protect the plant from insect attack.

In recent years consumers and agricultural producers are becoming more aware of the importance of protecting the environment. From this perspective biopesticides can provide significant benefits for the development of natural resources for sustainable practices for agricultural products. They are also fundamental components used in programs that benefit Integrated Pest Management (IPM) because their use decreases the quantity of synthetic pesticides necessary to control pests and plant diseases.

Due to the increasing demand for chemical-free agricultural products, there is a relevant growth in the global biopesticide market, in most cases exceeding the growth rates of traditional chemicals.

Biopesticides are included in the Plant Protection Products (PPPs) regulatory framework and manufacturers should meet the required standards for a sustainable use by reducing the risks and their impact on human health and on the environment. They must generate scientific data necessary to address concerns related to the identity, composition, potential adverse effects and environmental impact.

Eurofins BioPharma Product Testing Italy offers a full-service approach to support biopesticide manufacturers to meet the regulatory requirements of the European (Reg. EC No. 1107/2009) and US (EPA) market.

We perform physical, chemical, stability, ecotoxicological and efficacy analysis on active substances and formulations for use in the biopesticide activity.



GLP panel of analytical services:

- Active ingredient testing
- Impurities and metabolites testing
- Contaminants evaluation
- Analytical batch profile
- Biochemical and genetic strain identification of microorganisms
- Physical-chemical testing
- Stability studies (FAO, GIFAP, CIPAC, OPPTS guidelines)
- Physical hazards testing
- Set up and validation of analytical methods
- Residues testing
- Effectiveness testing on biopesticide
- Environmental behaviour on soil, water and sediments
- Ecotoxicological studies