

BioPharma Product Testing







Studies on biocides

Eurofins is **GLP** accredited by Italian Health Authorities to perform physical-chemical, stability, toxicological and eco-toxicological studies on active substances and formulations with a biocidal activity (disinfectant, insecticides, rodenticides, etc).

Eurofins is both **GLP** and **ISO17025** accredited to perform efficacy tests on disinfectant products applied on medical, veterinary and public fields (test available vs both microorganisms and viruses).

The wide number of protocols in our portfolio covers tests on all types of disinfectants, including liquid products, powders, spray, automatic noozle cans, wipes, gels. Protocols are both Phase2/Step1 and Phase2/Step2: suspension tests, surface carrier tests, airborne tests and test on healthy volunteers skin as well as preservative efficacy testing on using standard and customized protocols for different application and uses.

Since years we developed a study group, supporting customer with **Technical Expertise** and **Project Management** and a wide range of skills, capable to satisfy requirements on new biocidal substances and/or preparations to be placed into the EU market from the R&D stage to the 'go in the market' stage.

Why choose Eurofins?

- We perform a broad range of tests, under GLP or ISO17025 accreditation following OECD, CEN, ISO, ICH, AOAC and ASTM harmonized methods
- We are able to perform both standard and customized analysis by adapting common standard protocols (under GLP accreditation, if required).
- Our extensive testing experience, allows us to successfully meet your testing requirements in order to produce a biocidal substance or product, according to Biocidal Product Regulation (BPR) 528/2012 and following updates and guidances



- Analysis performed cover all BPR analytical requirements (both on raw materials and formulations)
- Our expertise in scientific problem solving can help you prevent costly production and delays.

Efficacy suspension and carrier tests vs microorganisms

- Against gram + and gram Bacteria
 CEN standards: EN 13727, EN14651,
 EN1656, EN14349, EN 1276, EN13697,
 EN16437
- Against Mycobacteria
 CEN standards: EN 14348, EN14563,
 FN14204
- Against Fungi (Yeasts and Moulds)
 CEN standards: EN 13624, EN 14562, EN 1657, EN 1650, EN 13697, EN 16438
- Against Spores
 CEN standards: EN 13704, AFNOR NF T 72-190, new tests vs C. difficile
- Against Legionella
 CEN standard: EN 13623
 and anti-algal efficacy

Efficacy studies for Skin Disinfectants

- Hygienic handrub & handwwash EN1499, EN1500
- Pre-surgical hand disinfection EN12791









Efficacy studies against Viruses

- CEN standards applicable EN14476, EN14675, prEN16777, EN13610
- Specific Virus
 Wide specific virus portfolio

Efficacy Airborne studies

- Standard studies vs microorganisms
 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 for Wipe Disinfectants

• EN16615
For Imbibed Wipes and custom options

Efficacy studies for Laundry products

- ASTM standards
 Launder-O-meter tests (Petrocci & Clarck method)
- EN16616
 Chemical and Chemo-thermal Disinfection

Efficacy studies vs other targets

- Biofilm EN ISO/TS 15883-5
- Insects
 Partnered
- Rodents
- Algae

Efficacy studies for US Market

ASTM and AOAC Standards
 For EPA and FDA registration of antimicrobials

Eco-toxicological & Biodegrability studies

- S Algal, Daphnia and Fish toxicity tests OECDs 201, 202, 203, 211
- Biodegradability
 OECD 310, ISO14593, ISO 11734, OECD
 209, OECD 224

Stability studies

- **CIPAC, BPU** (or ICH) stability studies management (shelf life or accelerated)
- Storage and analysis of samples in different conditions climatic chambers

Chemical studies on active substances and impurities

- Analytical method set-up through the best approaches
- Set-up and validation of new analytical methods to identify and quantify a.i. or impurities (GC, GC-MS, HPLC-UV, HPLC-ELSD, HPLC-MS, ICP-OES, ICP-MS, AAS, titration methods) according to SANCO, BPR, ICH, USP guidelines.
- Physical-Chemical properties according to OECD protocols

Toxicological studies

- Preliminary Tests
 OECD 439 skin corrosion test, OECD 431
 skin irritation test
- Acute Toxicity
 OECD 402 dermal toxicity test. OECD 403
 inhalation test, OECD 420 oral toxicity
 test ,OECD 405 eye irritation test, OECD
 429 sensitization test, OECD 437 and
 OECD 492 eye irritation test

PMC (Italian National Biocides Regulation)

- Efficacy studies
- Method validation & Stability studies

Services -

Chemistry/Biochemistry
Cell Banking Services
Facility & Process Validation
Method Development & Validation
Microbiology
Molecular & Cell Biology

Raw Materials Testing
Release Testing
Residuals & Impurities Testing
Stability Testing & Storage
Viral Clearance & Viral Safety
Professional Scientific StaffingSM

Facilities

Belgium Italy
Denmark Spain
France Sweden
Germany U.S.
Ireland

The largest network of harmonized bio/pharmaceutical GMP product testing labs worldwide.