

BioPharma Product Testing



Genetic Toxicology

Eurofins BioPharma Product Testing has more than 25 years of experience in performing biological safety and activity testing, including a broad range of Genetic Toxicology Studies.

Our certified team has great expertise in testing pharmaceuticals, chemicals, agrochemicals and mixtures, as well as medical devices. Eurofins BioPharma Product Testing will provide the scientific resources and expertise you need. Our laboratory team has extensive experience, not only in serving the testing needs of diverse clients, but also in conducting *in vitro* assay validation studies. Our tests comply with the current international guidelines (e.g. ICH, US-FDA, ISO, EMEA, OECD) and are performed in accordance with GLP (Good Laboratory Practice) to ensure their acceptability worldwide.

Why Choose Eurofins BioPharma Product Testing?

- Our familiarity with an array of different *in vitro* test systems enables us to provide contract testing services using the optimum assays to answer specific product safety and efficacy questions.
- In addition to standard testing, we offer consultation concerning your specific project with regard to scientific and regulatory requirements.
- We will provide you with the most reliable and timely results possible.
- We offer several standard tests as top priority with outstanding short turnaround time.

Customized Test Designs

The increasing number of new molecules synthesized in the pharmaceutical, chemical and cosmetic industries demands exceedingly the use of assays providing rapid results and requiring only small amounts of test material.

To respond to these market requirements, Eurofins BioPharma Product Testing offers miniaturized screening tests, allowing us to screen a large number of substances.

Gene Mutation

• Bacterial Mutation - Ames Mutagenicity (OECD 471)

Services

Chemistry/Biochemistry Cell Banking Services Facility & Process Validation GMP Manufacturing Method Development & Validation Microbiology Molecular & Cell Biology Raw Materials Testing Release Testing Stability Testing & Storage Viral Clearance & Viral Safety Professional Scientific Services®

- Mammalian Mutation Assay: Mouse Lymphoma Assay (OECD 490)
- HPRT-Test (OECD 476)
- Pig-a Assay

Chromosome Damage

in vitro Cytogenics

- Micronucleus Assay (Chinese Hamster Cell) (OECD 487)
- Micronucleus Assay (Human Lymphocyte) (OECD 487)
- Chromosome Aberration Test (Chinese Hamster Cells) (OECD 473)
- Chromosome Aberration Test (Human Lymphocytes) (OECD 473)
- Unscheduled DNA Synthesis (UDS) Test (Mammalian Liver Cells) (OECD 482)

in vivo* Cytogenics

- Micronucleus Assay (Peripheral Blood) (Rat or Mouse) (OECD 474)
- Micronucleus Assay (Bone Marrow) (Rat or Mouse) (OECD 474)
- Chromosome Aberration Test (Mammalian Bone Marrow) (OECD 475)
- Unscheduled DNA Synthesis (UDS) Test (Mammalian Liver Cells) (OECD 486)

Additional Tests

- Comet Assay (OECD 489)
- Embryonic Stem cell Test
- Syrian Hamster Embryo (SHE) Cell Transformation Assay
- Drug uptake in vitro
- *in vitro* Hepatocytes Proliferation Assay (mouse, rat, dog, human)
- Sponsor specific Assay Establishment

Italv

Spain

UK

US

Sweden

Netherlands

*All in vivo assays are performed by our partner lab

Facilities -

Australia Belgium Denmark France Germany Ireland The largest network of harmonized bio/pharmaceutical GMP product testing labs worldwide.