eurofins | 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 Design

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) [ISO 10993-3]
- Mammalian mutation assay: mouse lymphomaassay (OECD 490) [ISO 10993-3]
- HPRT-test (OECD 476) [ISO 10993-3]
- 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)
- 3D Skin Model combined with Micronucleus assay - EpiDerm® Model

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)

Chromosome Damage

- Comet assay (*in vitro and in vivo*) (OECD 489)
- Combination of Micronucleus and Comet Assay
- 3D Skin Model combined with Micronucleus assay - Phenion® Model

Additional Tests

- Embryonic stem cell test
- Drug uptake *in vitro*
- Hepatocyte proliferation assay *in vitro* (mouse, rat, dog, human)
- Sponsor specific assay establishment

Comprehensive GMP Testing Services

Method Development & Validation • Release Testing • Raw Materials Testing
Cell Banking Services • Virology Services • Facility & Process Validation
Chemistry • Biochemistry • Molecular & Cell Biology • Microbiology
Stability Testing & Storage • Primary & Secondary Package Testing

Flexible Service Models

Fee For Service (FFS)
Full-Time-Equivalent (FTE)
PSS Insourcing Solutions®

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