

Alternative Toxicology Testing Services

Eurofins BioPharma Product Testing is committed to the advancement of animal welfare and we encourage others to include human concern for animals as a core aspect of corporate social responsibility.

That is why Eurofins BioPharma Product Testing is a leader in safety testing without animals and deeply committed to the principles of the **3 R's of Replacement, Reduction and Refinement**.

Our evaluation methods incorporate a unique approach that lead to improved prediction of human results.

Our service portfolio includes methods for replacing the use of animals to evaluate **acute systemic toxicity, skin and eye irritation and skin allergenicity** and also reducing the use of animals for repeated-dose toxicity, carcinogenicity and reproductive toxicity.

Eurofins BioPharma Product Testing works closely with independent scientists and regulatory agencies to adopt methods to satisfy various regulations.

We are proactive in the development and use of *in vitro* methods partnering researchers and clients in pre-validation and validation studies.

Study Types for Screening and Regulatory Purpose:

in silico Safety Modeling

- Structure activity relationship by computerized models

Eye Irritancy

- Bovine corneal opacity and permeability test (BCOP; OECD 437)
- Hens egg chorionallantoic membrane test (HET-CAM)
- Reconstructed human corneal epithelial models (OCDE 492 and OCDE 492B)

Skin Corrosivity

- Reconstructed human skin equivalents (OECD 431)
- Corrositex® Membrane barrier test (OECD 435)

Skin Irritancy

- Reconstructed human skin equivalents (OECD 439)

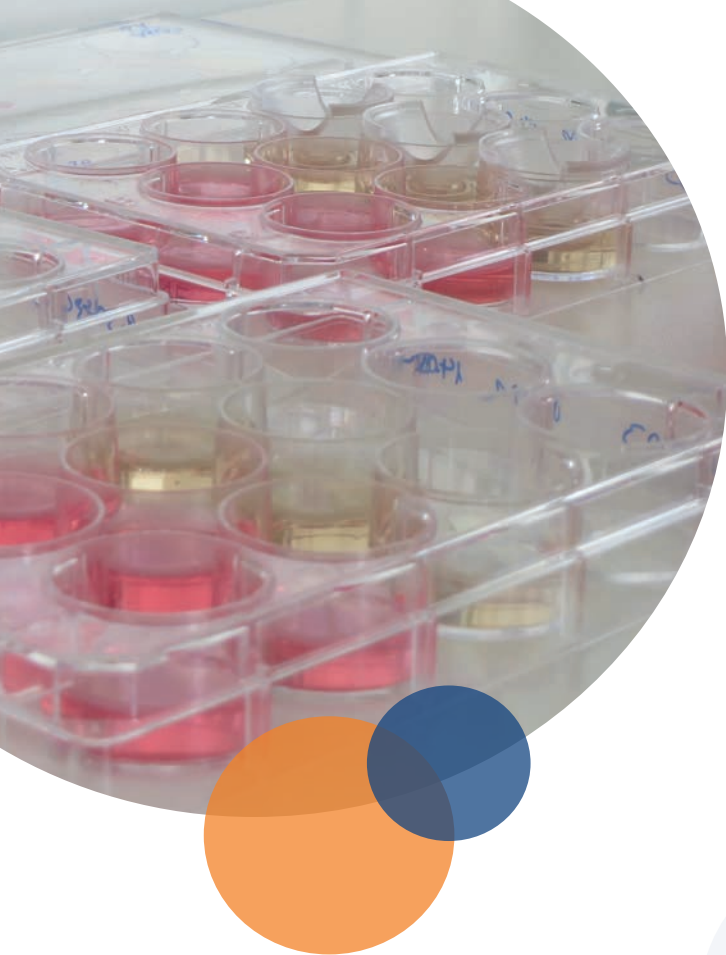
Skin Sensitization

- *in chemico*: Direct peptide reactivity (OECD 442 C)
- *in vitro*: KeratinoSens (OECD 442 D)
- *in vitro*: Activity of dendritic cells – h-Clat

Systemic Toxicity

- Assessment of starting dose for acute systemic toxicity using neutral red uptake
- Target organ toxicity with primary and cell lines from various organs
- Phototoxicity – Balb/3T3 neutral red uptake with artificial UV-light (OECD 432)
- Phototoxicity using human skin equivalents
- Immunotoxicity: Lymphocyte blastogenesis, natural killer cell activity, macrophage function
- Determination of cytokine release of peripheral blood mononuclear cells





Reproductive Toxicity/Endocrine Disruptor Activity

- Embryonic mouse stem cell test
- Steroidogenesis assay using H295R cells (OECD 456)
- Androgen receptor binding assay using cytosol of prostate (OPPTS 890.1150)
- Estrogen receptor binding assay using cytosol of uteri (OPPTS 1250)
- Aromatase assay using human supersomes (OPPTS 890.1200)
- Transcriptional estrogen receptor binding assay using HeLa cells (OPPTS 890.1300)
- Human skin equivalents (OECD 439)

Carcinogenicity

- Cell transformation assays (Bhas 42) assay and syrian hamster embryo (SHE) assay

Toxicokinetics – Barrier Systems

- Dermal penetration using flow-through diffusion cells and human and pig isolated skin systems
- Intestinal uptake using CaCo-2 absorption models

Toxicokinetics – Metabolism

- Interspecies comparative metabolism, metabolic stability, metabolic profiling
- Selective human cytochrome P450 metabolism
- Human cytochrome P450 inhibition
- MDR-(P-glycoprotein) interaction assay
- Glucuronidation
- Ethoxyresorufin-o-deethylase activity
- Pentoxyresorufin-o-dealkylase activity
- Benzyloxy-o-dealkylase activity

tLocal Tolerance

- Oral mucosal irritation using human reconstructed oral epithelium
- Vaginal epithelial irritation using human reconstructed vaginal epithelium
- Bladder epithelial irritation using human reconstructed bladder epithelium

Performance Testing

- Barrier efficacy test (human skin model)
- Lenitive efficacy test (human skin model)
- Wound healing efficacy (human skin model)
- Whitening efficacy (human skin model)

Mechanistic Investigations

- Reactive oxygen species: catalase, glutathionperoxidase, glutathion, thiobarbituric acid reactive substances, superoxidedismutase
- DNA adduct determination
- Antikinetochore antibody staining (CREST) of micronuclei in mammalian cells

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

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