



Bioassay

Eurofins performs the testing of about 350 batches of client material per year using a diverse range of bioassay types. Batch release testing is performed for both EU and US market.

For more than 17 years Eurofins has provided the scientific and experimental know-how to design and execute tailor-made bioassays in close collaboration with our clients. Our expertise in establishing and cultivating primary and permanent cell lines as well as the experience we gained from participation in various international round robin trials e.g. under the guidance of the WHO are at your disposal in this sophisticated service. *In vivo* and non cell-based bioassays of biopharmaceuticals are performed on a routine basis as well. Various pharmacopeial methods are established, e.g. for Erythropoietin (EPO), Filgrastim (GCSF), Urofollitropin (FSH) and Insulin.

Our development, validation and performance of bioassays/potency assays is US FDA approved and can be performed according to GLP and GMP regulations. Validation strategies are based on sponsors' requirements as well as international guidelines and recommendations (e.g. ICH, US-FDA, ISO, EMEA).

Available Bioassays

In Vitro Bioassays

- Cell proliferation
- Cell survival
- Reporter Gene
- ELISA
- PACE, KIRA etc.
- Binding Assays (e.g. SPA)
- CTL, ADCC and CDC

Assay Readouts

- Absorbance
- Luminescence
- Fluorescence
- Radioactivity (HTS module equipped scintillation counter)
- Analysis by flow cytometry (HTS module equipped, Six color)

In Vivo Bioassays

- Hormones, vaccines (immunopotency, immunogenicity)
- Established pharmacopeial methods for Erythropoietin, FSH, Insulin etc.

