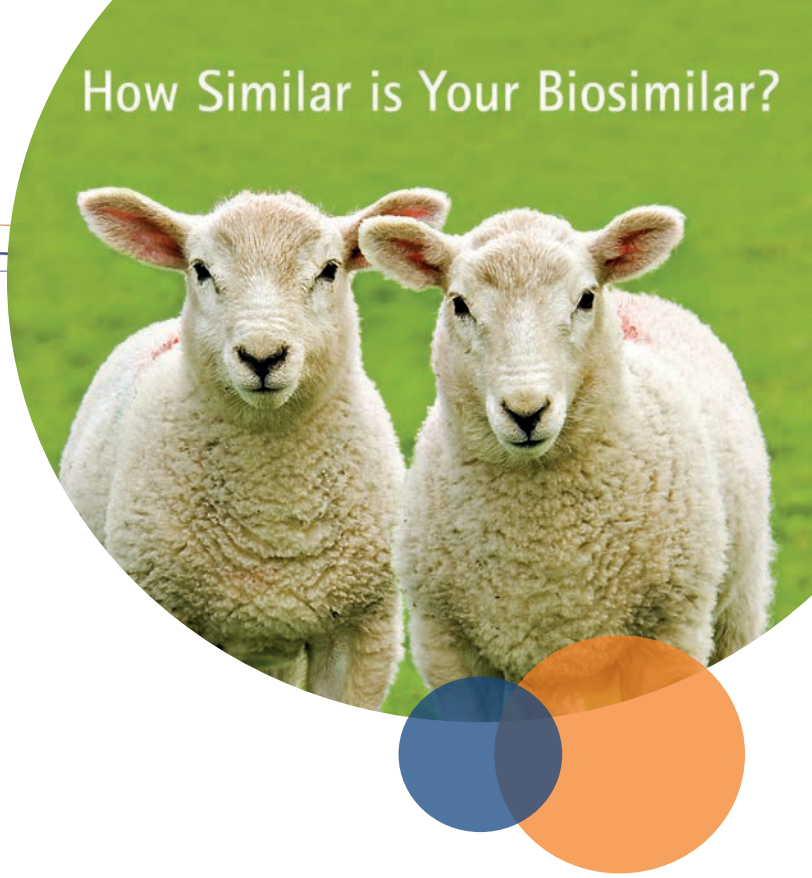
eurofins | BioPharma Product Testing



Biosimilar Potency Assays

As patents on popular biological medical products begin to expire, there is an emerging need for reliable testing capabilities to support biosimilar development.

Regulatory guidance recommends that extensive and robust comparability studies be performed on both physicochemical and functional attributes between the biosimilar product and its respective reference/innovator product.

Eurofins BioPharma Product Testing is proactively expanding our offering of validated cell based potency assays that are ready to use to test biosimilar drug substance and drug product samples, as well as to assist process development and validation.

In addition to the cell based potency assays being developed in the US, Eurofins BioPharma Product Testing Munich has method development and testing capabilities for Surface Plasmon Resonance (SPR) assays—alternative methods to study the binding activity/affinity of the biosimilar products to their intended target (and/or Fc receptors), which are frequently adopted as additional functional characterization assays. Amongst others, our Munich lab has also developed and qualified a set of characterization assays that can be used for a comparative study of innovator Simponi® and biosimilar product Golimumab.

We also collaborate with our colleagues at Eurofins BioPharma Product Testing Munich GmBH to transfer and co-validate methods to provide a global offering.

Why Choose Eurofins BioPharma Product Testing?

We have experience testing biosimilars for the top innovator targets.

We currently have validated cell based potency assays available to support the top three biosimilar products and have an aggressive schedule to bring additional assays on this year (see table on reverse).

By offering these assays at Eurofins locations in the US and Europe, we provide convenience in logistics for our clients who plan on launching products in both regions.

Comprehensive Services to Support Biosimilars

Our comprehensive offering of testing services enables us to support all aspects of your biosimilar development project, including:

- Full GMP Stability and Release Testing
- Biochemistry Characterization, meeting ICH guidelines (particularly ICH Q6B)
- cGMP Mammalian Cell Bank Manufacturing and Cell Line Characterization
- Viral Safety and Viral Clearance
- Lot Release for adventitious agents
- Microbiology
- Molecular and Cell Biology

Biosimilar Products	Assay Format	Status of Development & Validation	Target Timeline of Commercial Offering**
Filgrastim/ Pegfilgrastim	Proliferation assays using mNFS cell line	Fully validated	Available now
AdalimuMab	Apoptosis assay using U937 cell line	Fully validated	Available now
Etanercept	Proliferation assay using WEHI cell line	Fully validated	Available now
InflixiMab	Proliferation assay using WEHI cell line	Fully validated	Available now
BevacizuMab	hUVEC proliferations assay	Fully validated	Available now
	ADCC Reporter gene assay	Complete knowledge in method	Available upon client request
RituxiMab	ADCC Reporter gene assay	Fully validated	Available now
	CDC assay	Fully validated	Available now
TrastuzuMab	Proliferation assay using SK-BR3 cell line	Fully validated	Available now
	ADCC Reporter Gene Assay	Fully validated	Available now
GolimuMab	Full panel of lot release and characterization assay*	Fully validated	Available now
GLP-1 Receptor Agonists	Induction of cAMP	Method developed	Validation upon client request

*Full panels of GolimuMab assays are available at our site in Munich, Germany. The lot release assay will be transferred to our site in Lancaster, PA.

**We are sensitive to the unique needs of each of our biosimilar clients and will work with clients to prioritize development of a given method to support specific requests.