eurofins | BioPharma Product Testing



Golimumab (Simponi®) - Characterization panel to assess the biological activity

For more than 30 years Eurofins BioPharma Product Testing Munich has provided the scientific and experimental know-how to design and executes custom bioassays in close collaboration with our global clients.

Eurofins BioPharma Product Testing developed a panel of qualified *in vitro* cell based bioassays and surface plasmon resonance (SPR) assays to assess difference in the concentration–activity relationship between biosimilar products and their reference medicinal products. The studies for the key functional properties should be comparative and the methods sensitive enough to detect any difference in biological activity.

Golimumab is a fully human monoclonal IgG1 antibody that inhibits binding of TNF α to its receptor TNFR.

We have developed and qualified a set of characterization assays that can be used for a comparative study of innovator Simponi® and biosimilar product Golimumab. The panel consists of the relevant functional cell based and binding assays as shown in the Table.

The EMA/CHMP/BMWP/403543/2010 guideline on similar biological medicinal products containing monoclonal antibodies – non-clinical and clinical issues outlines this main strategy in evaluating the similarity of biosimilar and reference monoclonal antibody. In addition, the FDA Guidance for Industry, Scientific Considerations in Demonstrating Biosimilarity to a Reference Product and Quality Considerations in Demonstrating Biosimilarity of a Therapeutic Protein Product to a Reference Product should be considered.

Key Function	Assay Readout
Fab functional assay	• Cell based Bioassay/neutralization (Measurement of cell viability)
Binding to target antigen (Fab binding assays)	• Binding to soluble TNFα (SPR/Biacore) • Binding to membranous TNFα (FACS)
Fc functional assays	• ADCC reporter gene assay (using Promega ADCC kit) • CDC assay
Fc binding assays	• Binding to FcγRI/CD64 (SPR/Biacore) • FcγRIIA131R/CD32A (SPR/Biacore) • FcγRIIIA158V/CD16A (SPR/Biacore) • FcRn (SPR/Biacore) • Binding to Complement (C1q ELISA/C1q SPR)

eurofins | BioPharma Product Testing



Potency Assay Experience of the Eurofins global network

The bioassay teams of Eurofins BioPharma Product Testing Munich, Germany and Eurofins Lancaster Laboratories, US, work closely together to design and execute customized binding assays, cellular *in vitro* bioassays, as well as *in vivo* bioassays.

Our scientists have a wealth of experience to support development, licensing and commercial release of various biopharmaceutical products.

Biosimilars

We have established and validated various sponsor specific assays, pharmacopeia methods, as well as generic biosimilar characterization panels, including

- Golimumab, Etanercept, Adalimumab, Bevacizumab, Rituximab, Trastuzumab
- Interferon, Erythropoietin, (Peg-)Filgrastim, Somatropin

Any questions? Please contact us:
+49 (0) 89 899 650 0

Dr. Bettina Katterle - BettinaKatterle@eurofins.com
Dr. Stefanie Meier - StefanieMeier@eurofins.com

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®

With more than 25 Laboratories in 13 countries, Eurofins BioPharma Product Testing is the largest network of harmonized bio/pharmaceutical GMP product testing labs worldwide.

www.eurofins.com/biosimilars