

Certificate Of Analysis

Name: Etanercept
CAS No.: 185243-69-0
Cat No.: A851503
Batch No.: E23032018
Mfg.Date: 2018.03.23
Exp.Date: 2020.03.22

Items	Specifications	Results
Appearance	Colorless to milky white liquid	Conforms
pH value	Corresponds to reference standard	Conforms
Reduced CE-SDS	Heavy chain and light chain NLT 95.0%	98.3%
Non-reduced CE-SDS	Main peak NLT 90.0%	93.7%
SEC-HPLC	Main peak NLS 95.0%	99.1%
Isoelectric Point	Corresponds to reference standard	Conforms
Bacterial Endotoxins Test	≤ 0.125 EU/mg	Conforms
Ultraviolet Spectra Scanning	278±3nm	278
Residual Proteins of Host Cell	≤ 100 ppm	8
Exogenous Residual DNA	≤ 100 pg/mg	9
Residual protein A	≤ 100 ppm	16
Biological Activity	Compared with standard, the range of biological activity is from 80% to 125%	103%
Osmolality	Corresponds to reference standard	Conforms
Peptide mapping	Corresponds to reference standard	Conforms
N-terminal sequence	Corresponds to reference standard	Conforms
Conclusion	The product tested complies with the specifications.	

Storage condition: Sealed and stored at -70±15°C for long term storage and 2-8°C for short term storage(<1 months)

Checker:
