

Certificate of Analysis

Product name	Etanercept Biosimilar - Research Grade	
Product code	ICH4022	
Batch No.	IB1891	
Concentration	33.3mg/ml	
Expire Date	2027-11	
Storage condition	Sealed and stored at -70±15 °C for long term storage and 2-8 °C for short term storage (< 1 months)	
Test items	Quality standard	Results
1. pH value	Corresponds to reference standard	Pass
2. Purity		
2.1 Reduced CE-SDS	Heavy chain and light chain NLT 95.0%	99.0%
2.2 Non-reduced CE-SDS	Main peak NLT 90.0%	95.0%
2.3 SEC-HPLC	Main peak NLS 95.0%	98.0%
3. Isoelectric Point	Corresponds to reference standard	Pass
4. Bacterial Endotoxins	Test ≤ 0.125 EU/mg	Pass
5. Ultraviolet Spectra Scanning	278±3 nm	279nm
6. Residual Proteins of Host Cell	≤ 100 ppm	3 ppm
7. Exogenous Residual DNA	≤ 100 pg/mg	5 pg/mg
8. Residual protein A	≤ 100 ppm	8 ppm
9. Biological Activity	Compared with standard, the range of biological activity is from 80% to 125%	100%
10. Osmolality	Corresponds to reference standard	Pass
11. Peptide mapping	Corresponds to reference standard	Pass
12. N-terminal sequence	Corresponds to reference standard	Pass

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