



### Certificate of Analysis

**Trastuzumab/Herceptin**

**Brand Name :Biochempartner**

**CAS No.: 180288-69-1**

**Batch NO: 20190926**

**Stock Condition: Sealed and stored at -70±15 °C for long term storage and 2-8 °C for short term storage**

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%	99.8%
2.2 Non-reduced CE-SDS	Main peak NLT 90.0%	98.5%
2.3 SEC-HPLC	Main peak NLS 95.0	99.6%
3. Isoelectric Point	Corresponds to reference standard	Pass
4. Bacterial Endotoxins Test	≤ 0.125 EU/mg	Pass
5. Ultraviolet Spectra Scanning	278±3nm	278nm
6. Residual Proteins of Host Cell	≤ 100 pp	4 ppm
7. Exogenous Residual DNA	≤ 1 pg/mg	0.01pg/mg
8. Residual protein A	≤ 10 ppm	0.08 ppm
9. Biological Activity	Compared with standard, the range of biological activity is from 80% to 125%.	101%
10. Osmolality	Corresponds to reference standard	Pass
11. Peptide mapping	Corresponds to reference standard	Pass
12. N-terminal sequence	Corresponds to reference standard	Pass

Conclusion: Complies with In-house standard.

For and on behalf of  
SHANGHAI BIOCHEMPARTNER CO., LIMITED

Authorized Signature(s)

Kevin

QA manager :kexianxun

