



## Certificate of Analysis

Product Name:	Cetuximab				
Batch No.:	20190807	Mfg. Date:	2019-08-07	Analysis Date:	2019-08-10
Quantity:	100MG	CAS:	205923-56-4	Exp. Date:	2021-08-05
Storage:	Sealed and stored at -70±15 °C				
ITEM AND RESULT					
1. Concentration	5.0±0.2 mg/ml			5.0 mg/ml	
2. pH value	Corresponds to reference standard			Pass	
3. Purity					
3.1 Non-reduced CE-SDS	Main peak NLT 90.0%			98.8%	
3.2 SEC-HPLC	Main peak NLT 95.0%			99.6%	
4. Isoelectric Point	Corresponds to reference standard			Pass	
5. Bacterial Endotoxins Test	<1 EU/ml			<1 EU/ml	
6. Residual Proteins of Host Cell	≤100 ng/mg			<1 ng/mg	
7. Exogenous Residual DNA	≤100 pg/mg			<1 pg/mg	
8. Residual protein A	≤100 ng/mg			<1 ng/mg	
9. Biological Activity	Compared with standard, the range of biological activity is from 80% to 125%.			105%	
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

