



## Certificate of Analysis

**Product name:** Adalimumab  
**Batch No.** 202002  
**Manufacture Date** 2020/12/01  
**Expire Date** 2022/11/30  
**Storage condition** Sealed and stored at -70±15 °C

Test items	Quality standard	Results
1. Concentration	50.0±5.0 mg/ml	53.0 mg/ml
2. pH value	Corresponds to reference standard	Pass
3. Purity		
3.1 Non-reduced CE-SDS	Main peak NLT 90.0%	98.7%
3.2 SEC-HPLC	Main peak NLT 95.0%	99.5%
4. Isoelectric Point	Corresponds to reference standard	Pass
5. Bacterial Endotoxins Test	<10 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%.	103%
10. Osmolality	Corresponds to reference standard	Pass
11. Peptide mapping	Corresponds to reference standard	Pass
12. N-terminal sequence	Corresponds to reference standard	Pass

Reported by/Date  
Zhang Ziling

Approved by/Date  
Zhou Xiao