



Certificate of Analysis

Product name: Omalizumab
Batch No. 201801
Manufacture Date 2018/05/15
Expire Date 2020/05/14
Storage condition Sealed and stored at -70 ± 15 °C

Test items	Quality standard	Results
1. Concentration	125.0±12.5 mg/ml	125.7 mg/ml
2. pH value	Corresponds to reference standard	Pass
3. Purity		
3.1 Non-reduced CE-SDS	Main peak NLT 90.0%	98.6%
3.2 SEC-HPLC	Main peak NLT 95.0%	99.3%
4. Isoelectric Point	Corresponds to reference standard	Pass
5. Bacterial Endotoxins Test	<25 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
2018/06/14

Approved by/Date
Zhou Xiao
2018/06/14