



## Certificate of Analysis

**Product name:** Ipilimumab  
**Batch No.** 202001  
**Manufacture Date** 2020/07/20  
**Expire Date** 2022/07/19  
**Storage condition** Sealed and stored at  $-70\pm 15$  °C

Test items	Quality standard	Results
1. Concentration	$5.0\pm 0.5$ 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%	98.7%
3.2 SEC-HPLC	Main peak NLT 95.0%	99.6%
4. Isoelectric Point	Corresponds to reference standard	Pass
5. Bacterial Endotoxins Test	$<2$ EU/ml	$<1$ EU/ml
6. Residual Proteins of Host Cell	$\leq 100$ ng/mg	4 ng/mg
7. Exogenous Residual DNA	$\leq 100$ pg/mg	$<1$ pg/mg
8. Residual protein A	$\leq 100$ ng/mg	$<1$ ng/mg
9. Biological Activity	Compared with standard, the range of biological activity is from 80% to 125%.	104%
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  
2020/08/17

Approved by/Date  
Zhou Xiao  
2020/08/17