



Certificate of analysis

Product name: Trastuzumab

Cas number: 180288-69-1

Molecular Formula: C6470H10012N1726O2013S42

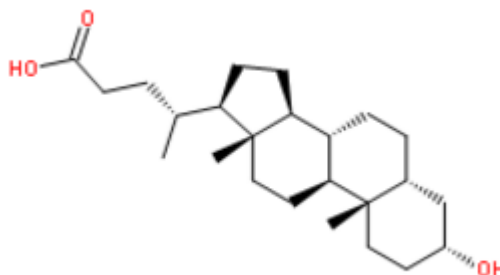
Molecular Weight: 145531.5

Date of production: Nov. 10, 2017

Batch NO: 20171110

Exp Date: Nov. 09, 2019

Chemical structure:



Items	Specifications	Results
Concentration	21.0 ± 2.1 mg/ml	21 mg/ml
PH value	Corresponds to reference standard	Pass
Purity	Non-reduced CE-SDS Main peak NLT 90.0%	97.3%
	SEC-HPLC Main peak NLT 95.0%	99.8%
Isoelectric Point	Corresponds to reference standard	Pass
Bacterial Endotoxins Test	Not more than 0.125 EU/mg	Conforms
Residual Proteins of Host Cell	Not more than 100 ppm	0.24 PPM
Exogenous Residual DNA	Not more than 100 pg/mg	0.02 pg/mg
Residual Protein A	Not more than 100 ppm	0.16 ppm
Biological Activity	Compared with standard, the range of biological activity is from 80% to 125%	104%
Osmolality	Corresponds to reference standard	Pass
Peptide mapping	Corresponds to reference standard	Pass
N-terminal sequence	Corresponds to reference standard	Pass

Storage condition: Sealed and stored at -70 ± 15 °C

Conclusion: It complies with Enterprise Standard.

Analyst: Zhao

Checker: Liu

Q.C Director: Fang

