



Certificate of analysis

Productname: Daratumumab

Cas number: 945721-28-8

Molecular Formula: C₆₄H₉₉N₁₇O₂₀S₄

Molecular Weight: 145391.67

Date of production: Sep. 28, 2018

Batch NO: 20180928

Exp Date: Sep. 27, 2020

Storage condition: Sealed and stored at ≤-30°C

Items	Specifications	Results
Concentration	20.0±2.0mg/ml	21.7mg/ml
PH value	Corresponds to reference standard	Pass
Purity	Non-reduced CE-SDS Mail peak NLT 90.0%	99.1%
	SEC-HPLC Mail peak NLT 95.0%	98.1%
Isoelectric Point	Corresponds to reference standard	Pass
Bacterial Endotoxins Test	< 3 EU/ml	< 1EU/ml
Residual Proteins of Host Cell	≤100 ng/mg	1 ng/mg
Exogenous Residual DNA	≤100 pg/mg	< 1 pg/mg
Residual protein A	≤100 ng/mg	< 1 ng/mg
Biological Activity	Compared with standard, the range of biological activity is from 80% to 125%	112%
Osmolality	Corresponds to reference standard	Pass
Peptide mapping	Corresponds to reference standard	Pass
N-terminal sequence	Corresponds to reference standard	Pass

Conclusion: It complies with the Enterprise Standard.

Analyst: Zhao

Checker: Liu

Q.C Director. Fang F