

Certificate of Analysis

Date of Testing: 2022-09-30 09:46:47
Date of Next Testing: 2025-09-29 09:46:47
Product Name: **Alirocumab**
CAS Number: 1245916-14-6
Specifications & Purity: ~75mg/ml in buffer , 95%
Lot #: I2228072
SKU #: **A302291**
Analysis: **131645**
Storage Temperature: Protected from light,Store at -20°C

Parameter	Limit Values	Result
Purity(SEC-HPLC)	95-100%	99.10 %
Bacterial endotoxins	≤ 15EU/ml	1.00 EU/ml
Biological Activity	80-125 (%)	101.00000 %
Residual Proteins of Host cell	≤ 100 mg/g	1.00000 mg/g
AResidual protein A	≤ 100 mg/g	1.00000 mg/g
Concentration	73-77 (mg/ml)	76.90 mg/ml
PH	5-7	5.80



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QA & QC Manager