



质量检验报告
CERTIFICATE OF ANALYSIS

产品名称(Product Name) : Sofituzumab vedotin (anti-MUC16)

英文名称(English Name) : Sofituzumab vedotin (anti-MUC16)

储存条件(Storage Condition) : 避免反复冻融;-80℃

CAS : 1418200-58-4

货号(Item No) : K14203

批号 (Lot. Number) : KK390814

检测日期(Date of Testing) : 2025-07-10

复测日期(Date of Retesting) : 2027-07-09

分析项目 SPECIFICATION PROPERTIES	技术指标 STANDARD	实测结果 RESULTS
Appearance	Colourless liquid	Colourless liquid
Purity(SDS-PAGE)	90%min	100.00000 %
Purity (SEC)	90%min	99.25000 %
Molecular Weight (Heavy Chain-R)	45.0-55.0(kD)	52.60000 kD
Molecular Weight (Light Chain-R)	20.0-30.0(kD)	27.10000 kD
Endotoxin Level < 1 EU/mg	Conform	Conform
(Free Drug) < 0.1%	Conform	Conform
Cell binding	Conform	Conform
Isotype	-	Human IgG1
Source	-	CHO supernatant
Concentration	8.8mg/mL	Conform
Buffer Solution	Supplied as a 0.22µm filtered solution in 100mM Pro-Ac,20mM Arg, pH 5.0	Conform

Quality Assurance : Xiaoyong Tan



Quality Control : Yunfei Zhu