



Certificate of Analysis

Product Name	Linacotide	Manufacture Date	Jan.29.2023
Batch Number	SW230129	Analysis Date	Jan.31.2023
Batch Quantity	100kg	Expiry Date	Jan.29.2025

ANALYSIS	SPECIFICATION	RESULT
Physical and chemical analysis		
Appearance	White to off-white powder	Qualified
Assay (HPLC)	≥ 98.0%	98.09%
Melting Point	233 °C	Qualified
Heavy metal	≤ 20ppm	Qualified
Solubility	Slightly soluble in water and sodium chloride solution (0.9%) DMF: 30 mg/ml DMSO: 30 mg/ml DMSO:PBS(pH 7.2) (1:4): 0.20 mg/ml	Qualified
Total Impurities	≤0.20%	0.16%
Ash content	≤0.10%	0.01%

Packing description	Sealed export grade drum & double of sealed plastic bag
Storage	Store in a cool and dry place, stay away from strong light and heat
Shelf life	2 years when properly stored

Quality Assurance Officer



Corrector

Analyst