

## CERTIFICATE OF ANALYSIS

Product Name:	Amikacin Sulfate		
Manufacturing Date	April 3, 2024	Expiry Date TO	February 28, 2028
Report Date	April 3, 2024	Batch No	H122402002
Packing	25KG/Drum	Batch Size	975KG
Analytical results			
Items	Specifications	Methods	Results
Appearance	White crystalline powder	USP	Conforms
Solubility	Freelysoluble in water	USP	Conforms
Identification	A.IR: The IR absorption spectrum conforms to that of reference standard	USP<197K>	Conforms
	B. HPLC: The retention time of the peak for Amikacin in the chromatogram of the sample solution corresponds to that in the chromatogram of the standard solution as obtained in the assay.	USP<621>	Conforms
	C.Chemical Reaction: It gives reaction of sulfates	USP<191>	Conforms
Optical Rotation	+76°~+84°	USP<781S>	+80°
Crystallinity	It Shows birefringence and extinction positions	USP<695>	Conforms
pH	2.0~4.0	USP<791>	3.3
Loss on Drying	≤13.0%	USP<731>	9.80%
Residue on Ignition	≤1.0%	USP<281>	0.02%
Residual Solvents	Methano1: ≤0.3%	USP<467>	0.20%
	Ethano1: ≤0.5%	USP<467>	Undetectable
	Acetonitrile: ≤ 0.041%	USP<467>	Undetectable
	Acetone: ≤ 0.5%	USP<467>	Undetectable
	Bacterial Endotoxins: 0.33EU/mg	USP<85>	<0.33EU/mg
Assay(driedsubstance)	674-786ug/mg of C22H43N5O13	USP<621>	726μg/mg
Microbial Limits	TAMC:≤10 <sup>3</sup> cfu/g	In-house	<10cfu/g
	TYMC:≤10 <sup>2</sup> cfu/g	In-house	<1cfu/g
	Escherichia Coli:Absence	In-house	Undetectable
Conclusion	Conforming to USP and in-house requirements		

Inspector: Carlifor Wu

Verifier: Jack He

