

## CERTIFICATE OF ANALYSIS

<b>Product Name:</b>	<b>Gentamicin Sulfate</b>		
<b>Batch No.</b>	221120022	<b>Report No.</b>	221019511
<b>Manufacturing Date</b>	Nov.,2022	<b>Expiry Date TO</b>	Oct.,2026
<b>Packing</b>	5KG/Tin,1Tin/Carton	<b>Quantity</b>	5 KG
<b>Analytical results</b>			
<b>Items</b>	<b>Specifications</b>		<b>Results</b>
<b>Characters</b>	A White or almost white powder.		Almost white powder.
<b>pH</b>	3.5~5.5		5.1
<b>Identification</b>	A: IR:the spectrum obtained is consistent with the specrum obtained with Gentamicin sulfate Rs		Complies
	B: Sulfate reaction: Positive		Complies
<b>Specific optical rotation</b>	+107°~+121°		+118°
<b>Methanol:</b>	Not more than 1.0 percent		/
<b>Content of Gentamicins</b>	C1+C2b :25%-50%		33.00%
	C1a:10%-35%		23.00%
	C2+C2a: 25%-55%		44.00%
<b>Loss on dring</b>	Not more than 18.0%		7.40%
<b>Residue on ignition</b>	Not more than 1.0%		0.20%
<b>Bacterial endotoxins</b>	Less than 0.71 EU/mg		<0.71 EU/mg
<b>Microbial limit</b>	Total aerobic microbial count	Not more than 10 <sup>3</sup> cfu/g	Less than 10 cfu/g
	Total yeast and mold count	Not more than 10 <sup>2</sup> cfu/g	Less than 10 cfu/g
<b>Assay</b>	No less than 590ug of gentamicin per mg (calculated on the dried basis)		673 ug/mg
	(hydrous substance)		623 ug/mg
<b>Conclusion</b>	This batch complies with the monograph for GENTAMICIN SULFATE in USP41		

Inspector: Carlifor Wu

Verifier: Jack He