

METAPHARMACEUTICAL

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0241123

29/11/2023



四川省长征药业股份有限公司

Sichuan Long March Pharmaceutical Co., Ltd.

PHARMACEUTICAL CO., LTD.

448 Changqing Road, Leshan, Sichuan 614000, P.R. China

CERTIFICATE OF ANALYSIS

Drug Name: Neomycin sulfate

Report No.	118	MFG Date	Jul.13,2022
Batch No.	SC-NM – 20220707	Date of Release	Jul.29,2022
Batch Size	1300Kilos Base	Expiration Date	Jan.12,2026
Test	Specification	Result	
Characters	Appearance:white or yellowish-white powder,hygroscopic. Solubility: very soluble in water,very slightly soluble in alcohol,practically insoluble in acetone.	Slightly yellow white powder, hygroscopic. Solubility:Complies	
Identification	A.(1)The retention time of a major peak meets the requirements. (2)ImpurityC: meets the requirements B.Positive	(1) Complies (2) Complies Positive	
pH	5.0 – 7.5	5.8	
Specific optical rotation (dried substance)	+53.5° – +59.0°	+57.3°	
Related substances (HPLC)	Impurity A : NMT2.0 %	0.2%	
	Impurity C: 3.0- 15.0 %	12.3%	
	Any other impurity: NMT 5.0 %	3.9%	
	Total of other impurities:NMT 15.0 %	5.5%	
Sulfate(anhydrous)	27.0 –31.0%	29.0%	
Loss on drying	NMT 8.0 %	6.2%	
Sulfated ash	NMT 1.0 %	0.3%	
Potency	NLT 680 IU/mg (dried substance)	695IU/mg (dried substance)	
		652IU/mg (as is)	
Conclusion: Complies with EP10.7			
Sodium Metabisulfite limit (internal)	NMT 0.4%		0.1%
Microbiological Contamination (internal):	TAMC cfu/g TYMC cfu/g E.Coli /g	10 ³ 10 ² absent	125 cfu/g 86 cfu/g Absent

Reported by

任子

Checked by

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Director of QC

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2022.07.29