



F. & A. PHARMA-Handels-GmbH
Bonhoeffering 41 • D - 46286 Dorsten • Germany
Phone: +49(0)2369-9261947 • Fax: +49(0)2369-9261950

METAPHARMACEUTICAL

N DE LOTE:

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02/09/2021



四川省长征药业股份有限公司

Sichuan Long March Pharmaceutical Co., Ltd.

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

CERTIFICATE OF ANALYSIS

Drug Name: Neomycin sulfate

Report No.	204	MFG Date	Oct.02,2020
Batch No.	SC-NM – 20201002	Date of Release	Oct.16,2020
Batch Size	1300 Kilos Base	Expiration Date	Apr.01,2024
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		6.3
Specific optical rotation (dried substance)	+53.5° – +59.0°		+57.9°
Related substances (HPLC)	Impurity A : NMT2.0 %		0.1%
	Impurity C: 3.0–15.0 %		10.7%
	Any other impurity: NMT 5.0 %		1.8%
	Total of other impurities:NMT 15.0 %		2.9%
Sulfate(anhydrous)	27.0 –31.0%		28.8%
Loss on drying	NMT 3.0 %		6.0%
Sulfated ash	NMT 1.0 %		0.4%
Potency	NLT 680 IU/mg (dried substance)		691IU/mg (dried substance) 650IU/mg (as is)
Conclusion: Complies with EP10.0			
Sodium Metabisulfite limit (internal)	NMT 0.4%		0.1 %
Microbiological Contamination (internal):	TAMC cfu/g 10 ³ TYMC cfu/g 10 ² E.Coli /g absent	61 cfu/g 28 cfu/g Absent	

Reported by

FE42

Checked by

W. J. Zhang

Director of QC

2020.10.16

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