

Lot: 0090417



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.	009	MFG Date	Jan.09,2017
Batch No.	SC-NM – 20170109	Date of Release	Jan.11,2017
Batch Size	1340 Kilos Base	Expiration Date	Jul.08,2020
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 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	6.4	
Specific optical rotation (dried substance)	+53.5° – +59.0°	+56.8°	
Related substances	Impurity A : NMT2.0 %	0.1%	
	Impurity C: 3.0- 15.0 %	14.7 %	
	Any other impurity: NMT 5.0 %	NMT 2.2%	
	Total of other impurities:NMT 15.0 %	4.0 %	
Sulfate(anhydrous)	27.0 –31.0%	29.4%	
Loss on drying	NMT 8.0 %	5.8 %	
Sulfated ash	NMT 1.0 %	0.4%	
Potency	NLT 680 IU/mg (dried substance)	693IU/mg (dried substance)	
		653 IU/mg(as is)	
Conclusion: Complies with EP8.0			
Remark: Sodium Metabisulfite limit NMT 0.4%(internal) 0.1 %			

Reported by

任小江

Checked by

王杰

Director of QC

张明

2017.01.11

Microbiological Contamination

TAMC cfu/g 10³
TYMC cfu/g 10²
E.Coli /g absent

Ph.Eur.2.6.12 Complies
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Ph.Eur.2.6.13 Complies

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