



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.	067	MFG Date	May.14,2015
Batch No.	SC-NM – 20150510	Date of Release	May.26,2015
Batch Size	1180 Kilos Base	Expiration Date	Nov.13,2018
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	6.3	
Specific optical rotation	+53.5° – +59.0°	+55.2°	
Related substances	Impurity A : NMT2.0 %	0.2 %	
	Impurity C: 3.0- 15.0 %	10.7 %	
	Any other impurity: NMT 5.0 %	NMT 2.1%	
	Total of other impurities:NMT 15.0 %	3.3 %	
Sulfate(anhydrous)	27.0 –31.0%	29.7 %	
Loss on drying	NMT 8.0 %	6.1 %	
Sulfated ash	NMT 1.0 %	0.3 %	
Potency	NLT 680 IU/mg (dried substance)	695 IU/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

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Checked by

任421

Director of QC

杜强

2015.05.26

Microbiological Contamination

TAMC	cfu/g	10 ³	ph.Eur.2.6.12	Complies
TYMC	cfu/g	10 ²	Ph.Eur.2.6.12	Complies
E.Coli	/g	absent	Ph.Eur.2.6.13	Complies

CEP NO :R1-CEP 2001-317-REV00