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四川省长征药业股份有限公司

Sichuan Long March Pharmaceutical Co., Ltd.

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CERTIFICATE OF ANALYSIS

Drug Name: **Neomycin sulfate**

Report No.	073	MFG Date	May.06,2013
Batch No.	SC-NM – 20130505	Date of Release	May.20,2013
Batch Size	920 Kilos Base	Expiration Date	Nov.05,2016
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	5.9	
Specific optical rotation	+53.5° – +59.0°	+56.0°	
Related substances	Impurity A : NMT2.0 %	0.2 %	
	Impurity C: 3.0- 15.0 %	11.8 %	
	Any other impurity: NMT 5.0 %	NMT 3.3 %	
	Total of other impurities:NMT 15.0 %	8.0 %	
Sulfate(anhydrous)	27.0 –31.0%	28.9 %	
Loss on drying	NMT 8.0 %	5.8 %	
Sulfated ash	NMT 1.0 %	0.5 %	
Potency	NLT 680 IU/mg (dried substance)	693 IU/mg (dried substance)	
		653 IU/mg(as is)	
Conclusion: Complies with EP7.0			
Remark: Sodium Metabisulfite limit NMT 0.4%(internal) 0.1 %			

Reported by

Checked by

Director of QC

Microbiological Contamination

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

Ph.Eur.2.6.12

Ph.Eur.2.6.12

Ph.Eur.2.6.13

Complies

Complies

Complies

CEP NO.:R1-CEP 2001-317-REV00

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