



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 sulphate

Lote: 0041211

Report No.	214	MFG Date	Aug.07,2011
Batch No.	SC-NM – 20110807	Date of Release	Aug.16,2011
Batch Size	1100 Kilos Base	Expiration Date	Feb.2015
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°		+56.8°
Related substances	Impurity A : NMT2.0 %		0.3 %
	Impurity C: 3 - 15 %		10.0 %
	Any other impurity: NMT 5 %		NMT1.9 %
	Total of other impurities:NMT 15 %		2.7 %
Sulphate(anhydrous)	27.0 –31.0%		29.3 %
Loss on drying	NMT 8.0 %		6.2 %
Sulphated ash	NMT 1.0 %		0.4 %
Potency	NLT 680 IU/mg (dried substance)		691 IU/mg (dried substance)
			648 IU/mg(as is)
Conclusion: Complies with EP7.0			
Remark: Sodium Metabisulfite limit NMT 0.4%(internal) 0.1 %			

Reported by

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Checked by

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Director of QC

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