



THREE GORGES YICHANG SANXIA PHARMACEUTICAL CO., LTD.

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CERTIFICATE OF ANALYSIS

ISSUING DATE:2015-04-10

PRODUCT NAME:NEOMYCIN SULPHATE	BATCH NO.:201504002
PACKING:20BOU/DRUM	MFG DATE:2015-04-01
QUANTITY:1540BOU	RE-TEST PERIOD:2019-03-30

Items	Specification:EP8.0	Results
Characteristics	White or yellowish-white powder, odorless or almost, hygroscopic	Complies
Identification	A; B The positive reaction.	Complies
Solubility	Very soluble in water, very slightly soluble in Alcohol, practically insoluble in acetone	Complies
PH	5.0-7.5	6.2
Specific optical rotation	+53.5° TO +59.0°	+58.1°
Related Substance (HPLC)	Impurity A	≤2.0%
	Impurity C	3.0%-15.0%
	Any other impurity	≤5.0%
	Total of other impurities	≤15.0%
	Any unspecified impurities	≤1.0%
	Disregard limit	≤1.0%
Sulphate	27.0%-31.0%	28.5%
Loss on drying	≤8.0%	5.1%
Sulphated ash	≤1.0%	0.19%
Microbiological Enumeration	TAMC ≤1000CFU/g; (EP7.0 chapter 5.1.4)	<10
	TYMC ≤100CFU/g; (EP7.0 chapter 5.1.4)	<10
Residual sodium bisulfite (as SO ₂ , %)	≤0.3%	0.21%
Assay	≥680I.U./mg(DRY)	688I.U./mg(DRY) 653I.U./mg(AS IS)
Conclusion: The product meets the requirements of EP8.0		

Analysts:

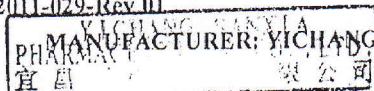
Yang Peifeng Ma Yongmei Jia Yumei

Supervisor:

Chen Yongqiang

THE BATCH HAS BEEN MANUFACTURED IN FULL COMPLIANCE WITH GMP NUMBER:鄂J0351, ISSUE DATE:2008/12/26, VALIDITY DATE:2015/12/31 AND "BATCH PRODUCTION RECORD CHECKED AND APPROVED."

COS NO.:RO-CEP 2011-029-Rev.01



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