



THREE GORGES

YICHANG SANXIA PHARMACEUTICAL CO., LTD.

NO.8, ZIYANG ROAD, DIANJUN DISTRICT, YICHANG CITY, HUBEI PROVINCE, P.R.CHINA

CERTIFICATE OF ANALYSIS

ISSUING DATE: 2016.11.16

PRODUCT NAME: NEOMYCIN SULPHATE	BATCH NO.: 201611016
PACKING: 20BOU/DRUM	MFG DATE: 2016.11.09
QUANTITY: 2240BOU	RE-TEST PERIOD: 2020.11.08

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°	+57.7°
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%	28.6%
Loss on drying	≤8.0%	4.7%
Sulphated ash	≤1.0%	0.35%
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%	0.24%
Assay	≥680 I.U./mg	690 I.U./mg(DRY) 658 I.U./mg(AS IS)
Conclusion: The product meets the requirements of EP8.0		

Analysts:

Yang Peifeng Lin Meifang Jia Yumei

Supervisor:

Chen Yongqiang

THE BATCH HAS BEEN MANUFACTURED IN FULL COMPLIANCE WITH GMP
NUMBER: HB20150194, ISSUE DATE: 2015/12/30, VALIDITY DATE: 2020/12/29 AND "BATCH
PRODUCTION RECORD CHECKED AND APPROVED."

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

MANUFACTURER: YICHANG SANXIA PHARMACEUTICAL CO., LTD.