



# YICHANG SANXIA PHARMACEUTICAL CO., LTD.

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

TELEPHONE NUMBER: 0086-717-6673625

## CERTIFICATE OF ANALYSIS

ISSUING DATE:2017-06-19

PRODUCT NAME:NEOMYCIN SULFATE	BATCH NO.:201706018
PACKING: 20BOU/DRUM	MFG DATE:2017-06-11
QUANTITY:900BOU	RE-TEST PERIOD:2021-06-10

Items	Specification:EP9.0	Results
Appearance	White or yellowish-white powder, hygroscopic	Complies
Identification	Should complies with A, B	Complies
Solubility	Very soluble in water, very slightly soluble in Alcohol, practically insoluble in acetone	Complies
pH	5.0-7.5	6.3
Specific optical rotation	+53.5° TO +59.0° (dried substance)	+57.6°
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%
Sulfate	27.0%-31.0%(dried substance)	28.9%
Loss on drying	≤8.0%	4.6%
Sulfated ash	≤1.0%	0.20%
Microbiological Enumeration	TAMC ≤1000CFU/g;(EP7.0 chapter 5.1.4) TYMC ≤100CFU/g; (EP7.0 chapter 5.1.4)	<10 <10
Residual sodium bisulfite (as SO <sub>2</sub> ,%)	≤0.3%	0.20%
Assay	≥680IU/mg(dried substance)	691 IU/mg(DRY) 659 IU/mg(AS IS)
Conclusion: The product meets the requirements of EP9.0		

Analysts:

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Supervisor:

Jia Yumei

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.:R1-CEP 2011-029-Rev 00

MANUFACTURER: YICHANG SANXIA PHARMACEUTICAL CO., LTD.

