Lot : 0170919

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

ISSUE DATE: 2019-02-11

PRODUCT NAME:NEOMYCIN SULFATE	BATCH NO.:201902001
PACKING: 20BOU/DRUM	MFG DATE:2019-02-02
QUANTITY: 1140BOU	RE-TEST DATE:2023-02-01

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	6.1
Specific optical rotation		+53.5° TO +59.0° (dried substance)	+57.0°
Related Substance (HPLC)	Impurity A	≤2.0%	0.07%
	Impurity C	3.0%-15.0%	12.1%
	Any other impurity	≤5.0%	1.6%
	Total of other impurities	≤15.0%	3.7%
	Any unspecified impurities	≤1.0%	Complies
	Disregard limit	≤1.0%	Complies
Sulfate		27.0%-31.0%(dried substance)	29.5%
Loss on drying		≤8.0%	5.1%
Sulfated ash		≤1.0%	0.24%
Microbiological Enumeration		TAMC ≤1000CFU/g;(EP9.0 chapter 5.1.4) TYMC ≤100CFU/g; (EP9.0 chapter 5.1.4)	<10 <10
Residual sodium bisulfite (as SO_2,%)		≤0.3%	0.21%
Assay		≥680IU/mg(dried substance)	685 IU/mg(DRY) 650 IU/mg(AS IS)
Conclusion: The product meets the requirements of EP9.0			

Analysts:
Feng Jingjing Lin Meifang Xu Fahui

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.