30/06/2022

YICHANG SANXIA PHARMACEUTICAL CO., LTD.

NO.8, ZIYANG ROAD, DIANJUN DISTRICT, YICHANG CITY, HUBEI PROVINCE, P.R.CHINA
TELEPHONE NUMBER: 0086-717-6673625

METAPHARMACEUTICAL

N DE LOTE: Q160622

CERTIFICATE OF ANALYSIS

ISSUE DATE: 2021.10.25

PRODUCT NAME: NEOMYCIN SULPHATE	BATCH NO.: 202110005
PACKING: 20 BOU /DRUM	MFG DATE: 2021.10.14
BATCH SIZE: 3100.00 BOU	RE-TEST DATE: 2025.10.13
QUANTITY: 1500 BOU	

Items		Specification:	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	6.2
Specific optical rotation		+53.5° TO +59.0° (dried substance)	+57.6°
Related Substance (HPLC)	Impurity A	≤2.0%	0.06%
	Impurity C	3.0%-15.0%	13.1%
	Any other impurity	≤5.0%	1.0%
	Total of other impurities	≤15.0%	1.0%
	Any unspecified impurities	≤1.0%	Complies
	Disregard limit	≤1.0%	Complies
Sulfate		27.0%-31.0%(dried substance)	28.4%
Loss on drying		≤8.0%	4.9%
Sulfated ash		≤1.0%	0.28%
Microbiological Enumeration		TAMC ≤1000CFU/g	<10
		TYMC ≤100CFU/g	<10
Residual sodium bisulfite (as SO_2,%)		≤0.3%	0.26%
Assay		≥680IU/mg(dried substance)	699IU/mg
Assay "as is"		Report Results	665IU/mg
Conclusion: The product meets the requirements of EP10.0			

Analysts/Date:

Supervisor/Date:

Final Batch Disposition: Approved (√) □

By:

COS NO.:R1-CEP 2011-029-Rev 01

MANUFACTURER: YICHANG SANXIA PHARMACEUTICAL CO., LTD.

宜昌三峡制药有限公司 05-20-2021