

METAPHARMACEUTICAL

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 人福医药	 Yichang Sanxia Pharmaceutical Co., Ltd.	硫酸新霉素英文报告单 (CEP) Neomycin Sulphate English Version COA (CEP)		
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YICHANG SANXIA PHARMACEUTICAL CO., LTD.

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

TELEPHONE NUMBER: 0086-717-6673625

CERTIFICATE OF ANALYSIS

ISSUE DATE: 2024.03.07

PRODUCT NAME: NEOMYCIN SULPHATE	BATCH NO.: 202402019
PACKING: 15BOU/DRUM, 20BOU/DRUM, 25KG/ DRUM	MFG DATE: 2024.02.19
BATCH SIZE: 2447.75 BOU	RE-TEST DATE: 2028.02.18
QUANTITY:	

Items	Specification:	Results
Appearance	White or yellowish-white powder, hygroscopic	Conforms
Identification	Should complies with A, B	Conforms
Solubility	Very soluble in water, very slightly soluble in Alcohol, practically insoluble in acetone	Conforms
pH	5.0-7.5	6.4
Specific optical rotation	+53.5° TO +59.0° (dried substance)	+57.1°
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%
Sulfate	27.0%-31.0%(dried substance)	28.2%
Loss on drying	≤8.0%	5.5%
Sulfated ash	≤1.0%	0.30%
Microbiological Enumeration	TAMC ≤1000CFU/g	<10
	TYMC ≤100CFU/g	<10
Residual sodium bisulfite (as SO ₂ , %)	≤0.3%	0.14%
Assay	≥680IU/mg(dried substance)	692IU/mg
Assay "as is"	Report Results	654IU/mg
Conclusion: The product meets the requirements of		

Analysts/Date: 3/7/2024

Final Batch Disposition: Approved (✓) □

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

Supervisor/Date: 3/7/2024

By: 3/7/2024

MANUFACTURER: YICHANG SANXIA PHARMACEUTICAL CO., LTD.

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