

METAPHARMACEUTICAL

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25/06/2025

 人福医药	 宜昌三峡制药有限公司 YichangSanxia Pharmaceutical Co.,Ltd	硫酸新霉素英文报告单 (CEP) Neomycin Sulphate English Version COA(CEP)	编号 No. A4-001001-3.0	页码 Page No. 1/1
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YICHANG SANXIA PHARMACEUTICAL CO., LTD.

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

TELEPHONE NUMBER: 0086-717-6673625

CERTIFICATE OF ANALYSIS

ISSUE DATE: 2024.11.2

PRODUCT NAME: NEOMYCIN SULPHATE	BATCH NO.: 202411011
PACKING: 15BOU/DRUM	MFG DATE: 2024.11.11
BATCH SIZE: 3510.00 BOU	RE-TEST DATE: 2028.11.10
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 ethanol(96 per cent), practically insoluble in acetone	Conforms
pH	5.0-7.5	6.3
Specific optical rotation	+53.5°TO +59.0°(dried substance)	+56.7°
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%
Sulfate	27.0%-31.0%(dried substance)	28.4%
Loss on drying	≤8.0%	5.0%
Sulfated ash	≤1.0%	0.3%
Microbiological Enumeration	TAMC ≤1000CFU/g	<10
	TYMC ≤100CFU/g	<10
Residual sodium bisulfite (as SO ₂ ,%)	≤0.3%	0.13%
Assay	≥680IU/mg(dried substance)	694IU/mg
Assay "as is"	Report Results	659IU/mg
Conclusion: The product meets the requirements of EP11		

Analysts/Date: 王磊 2024.11.21

Supervisor/Date: 杜娟 2024.11.21

Final Batch Disposition: Approved (✓) ☒

By: 杜娟 2024.11.21

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MANUFACTURER: YICHANG SANXIA PHARMACEUTICAL CO., LTD.