



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. A4-001001-1.1 页码 Page No. 1/1

YICHANG SANXIA PHARMACEUTICAL CO., LTD.

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TELEPHONE NUMBER: 0086-717-6673625

CERTIFICATE OF ANALYSIS

ISSUE DATE: 2021.09.07

PRODUCT NAME: NEOMYCIN SULPHATE	BATCH NO.: 202108035
PACKING: 20 BOU /DRUM	MFG DATE: 2021.08.25
BATCH SIZE: 1500.00 BOU	RE-TEST DATE: 2025.08.24
QUANTITY:	

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	6.1
Specific optical rotation	+53.5° TO +59.0° (dried substance)	+57.2°
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%	4.9%
Sulfated ash	≤1.0%	0.32%
Microbiological Enumeration	TAMC ≤1000CFU/g	<10
	TYMC ≤100CFU/g	<10
Residual sodium bisulfite (as SO ₂ ,%)	≤0.3%	0.17%
Assay	≥680IU/mg(dried substance)	687 IU/mg
Assay "as is"	Report Results	653 IU/mg
Conclusion: The product meets the requirements of EP10.0		

Analysts/Date: [Signature] 林科号 2021.09.07

Supervisor/Date: [Signature] 2021.09.07

Final Batch Disposition: Approved (✓)

By: [Signature] 2021.09.07

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

MANUFACTURER: YICHANG SANXIA PHARMACEUTICAL CO., LTD.