

Certificate of Analysis

Product name: Neomycini sulfas
Batch number / Weight: 24J08-B08-004933 / 25 g
Producer / Producer Batch Number: Yichang Sanxia Pharmaceutical Co., Ltd / 202211007
Analyzed according to: Ph.Eur. 11.5
Number of Analysis / Certificate no.: 24J08-B08 / QO0008825

	Requirement	Result	Unit	Standard remark
Appearance	White or yellowish-white powder, hygroscopic	Conform		
Identification A	Examine the chromatograms obtained in the test for related substances.	Conform		
Identification B	It gives reaction (a) of sulfates	Conform		
Specific optical rotation	(+53,5) - (+59,0)	+55,3		
pH	5,0 - 7,5	6,36		
Related substances	Acc. to Ph. Eur.	Conform		
Impurity A	<=2,0	<1,0	%	
Impurity C	3,0 - 15,0	14,9	%	
Any other impurity	<=5,0	<1,0	%	
Total of other impurities	<=15,0	<1,0	%	
Sulfate	27,0 - 31,0	27,19	%	
Loss on drying	<= 8,0	2,91	%	
Sulfated ash	<=1,0	0,34	%	
Assay	>= 680 (dried substance)	683	IU/mg	
TAMC	<= 10 ³	<10 ²	cfu/g	
TYMC	<= 10 ²	0	cfu/g	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CHMP/ICH/82260/2006	Conform		DP
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		DP

All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab FSNE LAB

Release:

18-12-2024
 Dominika Sottysik
 Qualified Person

Expiration: 8-11-2026

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.