



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 242311

Product:	NEOMYCIN SULPHATE
Lot:	242311
Expiry date:	12/04/2028
Reference:	Cumple PhEur11.6
Synonyms:	
Formula:	C ₂₃ H ₄₆ N ₆ O ₁₃ ·xH ₂ SO ₄
Molecular weight:	615(base g/mol)

Assay	Result	Specification	
Identification	Conform (A,B)		
Organoleptic properties	Conform		
pH	6,4	5,0 - 7,5	
Specific rotation	(+56,6)	(+53,5) - (+59,0)	
Related substances (HPLC)	Conform		
Sulphates	27,3%	27,0 - 31,0 %	
Antimicrobial power	696 UI/mg sps	>= 680 UI/mg sps	
Loss on drying	5,7 %	<= 8,0 %	
Sulphated ashes	0,25%	<= 1,0 %	
Elemental impurities	Conform	Test PhEur	#
Impurity A	< 1,0 %	<= 2,0 %	
Impurity C	10,8 %	3,0 - 15,0 %	
Any other impurity	1,7 %	<= 5,0 %	
Total impurities	4,3%	<= 15,0 %	
Organic solvents residues	Conform	Test PhEur	#
Nitrosamine impurities	Conform		#

Organoleptic characteristics: White or yellowish-white powder, hygroscopic. Very soluble in water, very slightly soluble in alcohol, practically insoluble in acetone.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 14/01/2025

Judgement:
APPROVED

Responsible: B.Chia

Technical director: Montserrat Enrique

Manufacturer: F01044 YICHANG SANXIA PHARMACEUTICAL CO.,LTD

Manufacturer batch: 202404014

Product	Name	Capacity	Batch
1162212	NEOMICINA SULFATO	10 g	242311-F-1

1162212	NEOMICINA SULFATO	10 g	242311-F-3
1162213	NEOMICINA SULFATO	25 g	242311-G-1
1162213	NEOMICINA SULFATO	25 g	242311-G-3
1162214	NEOMICINA SULFATO	1 kg	242311-P-1
1370112	NEOMICINA SULFATO (FLB)	10 g	242311-F-2
1370112	NEOMICINA SULFATO (FLB)	10 g	242311-F-4
1370113	NEOMICINA SULFATO (FLB)	25 g	242311-G-2
1370113	NEOMICINA SULFATO (FLB)	25 g	242311-G-4
1370150	NEOMICINA SULFATO (FLB)	100 g	242311-J-1
1370150	NEOMICINA SULFATO (FLB)	100 g	242311-J-2

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

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