acofarma

ANALYSIS CERTIFICATE

Lot/Analysis/Analysis Nº: 251756

Product:	NEOMYCIN SULPHATE
Lot:	251756
Expiry date:	07/01/2029
Reference:	Cumple PhEur11.8
Synonyms:	
Formula:	C23H46N6O13·xH2SO4
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	+57,2	(+53,5) - (+59,0)	
Related substances (HPLC)	Conform		
Sulphates	27,2 %	27,0 - 31,0 %	
Antimicrobial power	702 UI/mg sps	>= 680 UI/mg sps	
Loss on drying	5,0 %	<= 8,0 %	
Sulphated ashes	0,29 %	<= 1,0 %	
Elemental impurities	Conform	Test PhEur	#
Impurity A	< 1,0 %	<= 2,0 %	
Impurity C	11,0 %	3,0 - 15,0 %	
Any other impurity	1,6 %	<= 5,0 %	
Total impurities	3,3 %	<= 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: 20/10/2025

Judgement:
APPROVED

Responsible: B. Chia
Technical director: Montserrat Enrique
Manufacturer: F01044 YICHANG SANXIA PHARMACEUTICAL CO.,LTD
Manufacturer batch: 202501007

Product	Name	Capacity	Batch
1162212	NEOMICINA SULFATO	10 g	251756-F-2

1162213	NEOMICINA SULFATO	25 g	251756-G-1
1162213	NEOMICINA SULFATO	25 g	251756-G-2
1162214	NEOMICINA SULFATO	1 kg	251756-P-1
1162214	NEOMICINA SULFATO	1 kg	251756-P-2
1370112	NEOMICINA SULFATO (FLB)	10 g	251756-F-1
1370150	NEOMICINA SULFATO (FLB)	100 g	251756-J-1

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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