



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 233511

Product:	NEOMYCIN SULPHATE
Lot:	233511
Expiry date:	20/11/2025
Reference:	Cumple PhEur11.2
Synonyms:	
Formule:	C ₂₃ H ₄₆ N ₆ O ₁₃ ·xH ₂ SO ₄
Poids moléculaire:	615(base g/mol

Assay	Result	Specification	
Identification	Conform (A,B)		
Organoleptic properties	Conform		
pH	6,1	5,0 - 7,5	
Specific rotation	+55,6	(+53,5) - (+59,0)	
Related substances (HPLC)	Conform		
Sulphates	28,1 %	27,0 - 31,0 %	
Antimicrobial power	682 UI/mg sps	> 680 UI/mg sps	
Loss on drying	6,0 %	<= 8,0 %	
Sulphated ashes	0,10 %	<= 1,0 %	
Elemental impurities	Conform	Test PhEur	#
Impurity A	< 1,0 %	<= 2,0 %	
Impurity C	11,6 %	3,0 - 15,0 %	
Any other impurity	2,4 %	<= 5,0 %	
Total impurities	4,0 %	<= 15,0 %	
Organic solvents residues	Conform	Test PhEur	#

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: 26/10/2023

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00429 SICHUAN LONG MARCH PHARMACEUTICAL CO., LTD.

Manufacturer batch: SC-NM-20220512

Produit	Nom	Capacité	Lot
1162212	NEOMICINA SULFATO	10 g	233511-F-1
1162212	NEOMICINA SULFATO	10 g	233511-F-3

1162212	NEOMICINA SULFATO	10 g	233511-F-5
1162213	NEOMICINA SULFATO	25 g	233511-G-1
1162213	NEOMICINA SULFATO	25 g	233511-G-3
1162213	NEOMICINA SULFATO	25 g	233511-G-5
1162213	NEOMICINA SULFATO	25 g	233511-G-6
1162214	NEOMICINA SULFATO	1 kg	233511-P-1
1162214	NEOMICINA SULFATO	1 kg	233511-P-2
1162214	NEOMICINA SULFATO	1 kg	233511-P-3
1370112	NEOMICINA SULFATO (FLB)	10 g	233511-F-2
1370112	NEOMICINA SULFATO (FLB)	10 g	233511-F-4
1370113	NEOMICINA SULFATO (FLB)	25 g	233511-G-2
1370113	NEOMICINA SULFATO (FLB)	25 g	233511-G-4
1370150	NEOMICINA SULFATO (FLB)	100 g	233511-J-1
1370150	NEOMICINA SULFATO (FLB)	100 g	233511-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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