



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 223922

Product:	TOBRAMYCIN SULPHATE
Lot:	223922
Expiry date:	24/05/2026
Reference:	Cumple USP-NF2022-2
Synonyms:	
Formula:	(C18H37N5O9)2·5H2SO4
Molecular weight:	1425,45 g/mol

Assay	Result	Specification	
Sterility	NA	Test USP	#
Sulphated ashes	0,04 %	<= 1,0 %	
Moisture - K.F.	0,85 %	<= 2,0 %	
Elemental impurities	Conform	Test USP	#
Assay (HPLC)	739 mcg/mg	634 - 739 mcg/mg	
Bacterial endotoxins	NA	Test USP	#
Residual solvent: Acetaldehyde	< 450 ppm	<= 450 ppm	#
Residual solvent: Ethanol	< 5000 ppm	<= 5000 ppm	#
Cromatographic purity	< 1,0 %	<= 1,0 %	
pH aqueous solution 4%	7,6	6,0 - 8,0	
Organoleptic properties	Conform		
Identification	Conform (A,B,C)	Test USP (A,B,C)	

Organoleptic characteristics: White or almost white, crystalline powder. Freely soluble in water, practically insoluble in ethanol.

Conservation: In tightly closed containers.

Date of analysis: 29/09/2022

Judgement:
APPROVED

Responsible: C. Codina

Technical director: Montserrat Enrique

Manufacturer: F00091 LIVZON GROUP FUZHOU FUXING PPHARMACEUTICAL CO.,LTD.,

Manufacturer batch: TB2205002

Product	Name	Capacity	Batch
1186696	TOBRAMICINA SULFATO	10 g	223922-F-1
1186696	TOBRAMICINA SULFATO	10 g	223922-F-2
1186697	TOBRAMICINA SULFATO	100 g	223922-J-1
1186697	TOBRAMICINA SULFATO	100 g	223922-J-2
1186697	TOBRAMICINA SULFATO	100 g	223922-J-3

1186697	TOBRAMICINA SULFATO	100 g	223922-J-4
1186700	TOBRAMICINA SULFATO	1 kg	223922-P-1
1186700	TOBRAMICINA SULFATO	1 kg	223922-P-2
1186700	TOBRAMICINA SULFATO	1 kg	223922-P-3
1186700	TOBRAMICINA SULFATO	1 kg	223922-P-4

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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