



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 213158

Product:	TOBRAMYCIN SULPHATE
Lot:	213158
Expiry date:	27/04/2025
Reference:	Cumple USP43
Synonyms:	
Formula:	(C18H37N5O9)2·5H2SO4
Molecular weight:	1425,45 g/mol

Assay	Result	Specification	#
Bacterial endotoxins	NA	Test USP	#
Assay (HPLC)	721 mcg/mg	634 - 739 mcg/mg	
Sulphated ashes	0,00 %	<= 1,0 %	
Sterility	Conform	Test USP	#
Residual solvent: Ethanol	<= 5000 ppm	<= 5000 ppm	#
Identification	Confome (A,B,C)	Test USP (A,B,C)	
Organoleptic properties	Conform		
Residual solvent: Acetaldehyde	<= 450 ppm	<= 450 ppm	#
Elemental impurities	Conform	Test USP	#
Moisture - K.F.	1,3 %	<= 2,0 %	
pH aqueous solution 4%	7,5	6,0 - 8,0	
Cromatographic purity	<= 0,1 %	<= 1,0 %	

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

Conservation: In tightly closed containers.

Date of analysis: 06/07/2021

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

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

Manufacturer batch: TB2104001

Product	Name	Capacity	Batch
1186696	TOBRAMICINA SULFATO	10 g	213158-F-1
1186696	TOBRAMICINA SULFATO	10 g	213158-F-2
1186697	TOBRAMICINA SULFATO	100 g	213158-J-1
1186697	TOBRAMICINA SULFATO	100 g	213158-J-2
1186700	TOBRAMICINA SULFATO	1 kg	213158-P-1

1186700

TOBRAMICINA SULFATO

1 kg

213158-P-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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