



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 241860

Product:	TOBRAMYCIN SULPHATE
Lot:	241860
Expiry date:	06/08/2028
Reference:	Cumple USP-NF2024-2
Synonyms:	
Formule:	(C18H37N5O9)2·5H2SO4
Poids moléculaire:	1425,45 g/mol

Assay	Result	Specification	
Organoleptic properties	Conform		
pH aqueous solution 4%	7,5	6,0 - 8,0	
Cromatographic purity	< 1,0 %	<= 1,0 %	
Elemental impurities	Conform	Test USP	#
Moisture - K.F.	0,86 %	<= 2,0 %	
Sulphated ashes	0,10 %	<= 1,0 %	
Sterility	NA	Test USP	#
Bacterial endotoxins	Conform	Test USP	#
Assay (HPLC)	687 mcg/mg	634 - 739 mcg/mg	
Residual solvent: Ethanol	<= 5000 ppm	<= 5000 ppm	#
Residual solvent: Acetaldehyde	<= 450 ppm	<= 450 ppm	#
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: 17/10/2024

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

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

Manufacturer batch: TB2408001

Produit	Nom	Capacité	Lot
1186697	TOBRAMICINA SULFATO	100 g	241860-J-1
1186700	TOBRAMICINA SULFATO	1 kg	241860-P-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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