



CERTIFICADO DE ANÁLISIS (COA)

Producto: Gentamicina Sulfato
CAS N°: 1405-41-0

CERTIFICATE OF ANALYSIS

CAS NO. 1405-41-0

Product Name: Gentamicin Sulphate BP2002/EP4

Batch No.	210411006	Manufacturing Date	APR.,2021
Reporting No.	212014100	Expiry Date	MAR.,2025
Package Size	5 BOU /Tin, 2Tin/Cartron	Quantity	/
Analytical results			
Items	Specifications		Results
Characters	A white or almost white powder, freely soluble in water, Practically insoluble in alcohol and in ether .		Complies
Identification	Tests according to monograph		Complies
Appearance of solution	Clear and not more intensely colored than degree 6 of the Range of reference solutions of the most appropriate color		Complies
pH	3.5 to 5.5		4.6
Specific optical rotation	+107° to +121°		+117°
Methanol	Not more than 1.0 percent		Complies
Composition	C ₁ : 25.0 to 50.0 per cent		26.7%
	C _{1a} : 10.0 to 35.0 per cent		22.8%
	C _{2a} + C ₂ : 25.0 to 55.0 per cent		50.5%
Water	Not more than 15.0 per cent		6.8%
Sulphated ash	Not more than 1.0 per cent		0.3%
Sulphate	32.0 to 35.0 per cent		33.4%
Bacterial endotoxins	Less than 1.67 IU/mg		Less than 0.71 IU/mg
Microbial limit	Total Aerobic Microbial Count	Not more than 1000 cfu/g	10 cfu/g
	Total yeast and mold Count	Not more than 100 cfu/g	Less than 10 cfu/g
Assay	Not less than 590 IU/ mg(anhydrous substance)		668 IU/mg
	(hydrous substance)		623 IU/mg
Conclusion :complies with the standard of BP2002/EP4			

Approver:

Reviewer :

Reporter :

El presente documento es copia fiel del original.