



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 250783

Product:	GENTAMICIN SULPHATE
Lot:	250783
Expiry date:	20/02/2027
Reference:	Cumple PhEur11.7
Synonyms:	
Formula:	
Molecular weight:	g/mol

Assay	Result	Specification	
Identification	Conform (B,C)		
Organoleptic properties	Conform		
Appearance of solution	Conform	Test PhEur	
pH	5,0	3,5 - 5,5	
Composition (HPLC)	Conform		
Specific rotation	(+115)	(+107) - (+121)	
Methanol (GC)	< 1,0 %	<= 1,0 %	#
Moisture - K.F.	4,2 %	<= 15,0 %	
Sulphated ashes	0,90 %	<= 1,0 %	
Bacterial endotoxins	NA	< 0,71 UI/mg	#
Sulphates	32,3 %	32,0 -35,0 %	
Antimicrobial power	635 UI/mg s.p.s	>= 590 U.I./mg s.p.s	
Related substances (HPLC)	Conform		
Elemental impurities	Conform	Test PhEur	#
Gentamicin C1	31,9 %	25,0 - 45,0 %	
Gentamicin C1a	17,6 %	10,0 - 30,0 %	
Sum of gentamicins C2,C2a and C2b	50,4 %	35,0 - 55,0 %	
Impurity A	< 0,5 %	<= 3,0 %	
Impurity B	0,7 %	<= 3,0 %	
Any other impurity	0,6 %	<= 3,0 %	
Total impurities	1 %	<= 10 %	
Organic solvents residues	Conform		#

Organoleptic characteristics: White or almost white, hygroscopic powder. Freely soluble in water, practically insoluble in ethanol (96 per cent).

Conservation: In tightly closed containers. Protect from moisture.

Date of analysis: 12/05/2025

Responsible: B. Chia

Judgement:
APPROVED

Technical director: Montserrat Enrique

Manufacturer: F00345 FUJIAN FUKANG PHARMACEUTICAL CO., LTD.

Manufacturer batch: FG2302046

Product	Name	Capacity	Batch
1147362	GENTAMICINA SULFATO	1 g	250783-D-1
1147362	GENTAMICINA SULFATO	1 g	250783-D-2
1147362	GENTAMICINA SULFATO	1 g	250783-D-3
1147363	GENTAMICINA SULFATO	5 g	250783-E-1
1147363	GENTAMICINA SULFATO	5 g	250783-E-2
1147363	GENTAMICINA SULFATO	5 g	250783-E-3
1147364	GENTAMICINA SULFATO	25 g	250783-G-2
1147364	GENTAMICINA SULFATO	25 g	250783-G-3
1147364	GENTAMICINA SULFATO	25 g	250783-G-4
1147366	GENTAMICINA SULFATO	500 g	250783-O-1
1147366	GENTAMICINA SULFATO	500 g	250783-O-2
1200169	GENTAMICINA SULFATO	100 g	250783-J-1
1200169	GENTAMICINA SULFATO	100 g	250783-J-2
1200169	GENTAMICINA SULFATO	100 g	250783-J-3

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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