



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 233512

Product:	GENTAMICIN SULPHATE
Lot:	233512
Expiry date:	03/01/2027
Reference:	Cumple PhEur11.2
Synonyms:	
Formula:	
Molecular weight:	g/mol

Assay	Result	Specification	
Identification	Conform (B,C)		
Organoleptic properties	Conform		
Appearance of solution	Conform	Test PhEur	
pH	4,6	3,5 - 5,5	
Composition (HPLC)	Conform		
Specific rotation	+118	(+107) - (+121)	
Methanol (GC)	< 1,0 %	<= 1,0 %	
Moisture - K.F.	7,0 %	<= 15,0 %	
Sulphated ashes	0,02 %	<= 1,0 %	
Bacterial endotoxins	NA	< 0,71 UI/mg	#
Sulphates	32,1 %	32,0 -35,0 %	
Antimicrobial power	673 U.I./mg s.p.s	>= 590 U.I./mg s.p.s	
Related substances (HPLC)	Conform		
Elemental impurities	Conform	Test PhEur	#
Gentamicin C1	33,2 %	25,0 - 45,0 %	
Gentamicin C1a	19,8 %	10,0 - 30,0 %	
Sum of gentamicins C2,C2a and C2b	47,0 %	35,0 - 55,0 %	
Impurity A	< 0,5 %	<= 3,0 %	
Impurity B	< 0,5 %	<= 3,0 %	
Any other impurity	0,5 %	<= 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: 26/10/2023

Responsible: M. Mesa

Judgement:
APPROVED

Technical director: Montserrat Enrique

Manufacturer: F00345 FUJIAN FUKANG PHARMACEUTICAL CO., LTD.

Manufacturer batch: FG2301004

Product	Name	Capacity	Batch
1147362	GENTAMICINA SULFATO	1 g	233512-D-1
1147362	GENTAMICINA SULFATO	1 g	233512-D-2
1147362	GENTAMICINA SULFATO	1 g	233512-D-3
1147362	GENTAMICINA SULFATO	1 g	233512-D-4
1147362	GENTAMICINA SULFATO	1 g	233512-D-5
1147363	GENTAMICINA SULFATO	5 g	233512-E-1
1147363	GENTAMICINA SULFATO	5 g	233512-E-2
1147363	GENTAMICINA SULFATO	5 g	233512-E-3
1147363	GENTAMICINA SULFATO	5 g	233512-E-4
1147363	GENTAMICINA SULFATO	5 g	233512-E-5
1147363	GENTAMICINA SULFATO	5 g	233512-E-6
1147364	GENTAMICINA SULFATO	25 g	233512-G-1
1147364	GENTAMICINA SULFATO	25 g	233512-G-3
1147364	GENTAMICINA SULFATO	25 g	233512-G-4
1147364	GENTAMICINA SULFATO	25 g	233512-G-5
1147364	GENTAMICINA SULFATO	25 g	233512-G-6
1147366	GENTAMICINA SULFATO	500 g	233512-O-1
1147366	GENTAMICINA SULFATO	500 g	233512-O-2
1147366	GENTAMICINA SULFATO	500 g	233512-O-3
1147366	GENTAMICINA SULFATO	500 g	233512-O-4
1147366	GENTAMICINA SULFATO	500 g	233512-O-5
1147366	GENTAMICINA SULFATO	500 g	233512-O-6
1200169	GENTAMICINA SULFATO	100 g	233512-J-1
1200169	GENTAMICINA SULFATO	100 g	233512-J-2
1200169	GENTAMICINA SULFATO	100 g	233512-J-3
1200169	GENTAMICINA SULFATO	100 g	233512-J-4
1200169	GENTAMICINA SULFATO	100 g	233512-J-5
1200169	GENTAMICINA SULFATO	100 g	233512-J-6
1370111	GENTAMICINA SULFATO (FLB) (INACTIVO)	25 g	233512-G-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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