



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 241939

Product:	COLISTIN SOLPHATE
Lot:	241939
Expiry date:	30/04/2028
Reference:	Cumple PhEur11.5
Synonyms:	Polimixina E sulfato.
Formula:	
Molecular weight:	g/mol

Assay	Result	Specification	
Impurity B	< 0,4 %	<= 4,0 %	=
Any impurity; not more than 4 >= 1.0%	2,0 % ; <= 4	<= 2,5 % ; <= 4	=
Total impurities	10,3 %	<= 11,0 %	=
Polymyxin E1-I	< 0,35 %	<= 8,5 %	
Polymyxin E3	2,6 %	<= 5,5 %	
Identification	Conform (B,E)		
Polymyxin E1-7MOA	3,1 %	<= 5,0 %	
Organoleptic properties	Conform		
Polymyxin E6	0,86 %	Polymyxin E6	
pH	4,3	4,0 - 6,0	=
Polymyxin E1-Nva	0,50 %	<= 4,5 %	
Related substances (HPLC)	Conform		=
Sum of polymyxins E4 and E2-Val	2,1 %	<= 3,0 %	
Sulphates	16,9 %	16,0 - 18,0 %	=
Poymyxin E2-I	0,65 %	<= 2,5 %	
Loss on drying	2,9 %	<= 3,5 %	
Polymyxin 2,3-dehidro E1	< 0,35 %	<= 1,5 %	
Sulphated ashes	0,2 %	<= 1,0 %	=
Sum of polymyxins	91,7 %	>= 86,0 %	
Antimicrobial power	23334 UI/mg s.p.s	>= 19000 UI/mg s.p.s	
Residual solvent: Ethanol	< 5000 ppm	<= 5000 ppm	#
Composition (HPLC)	Conform		
Elemental impurities	Conform	Test PhEur	#
Nitrosamine impurities	Conform	Test PhEur	#

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

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 21/10/2024

Judgement:
APPROVED

Responsible: B.Chia

Technical director: Montserrat Enrique

Manufacturer: F00433 LABORATORIUM OFICHEM B.V.

Manufacturer batch: 2404018.1224

Product	Name	Capacity	Batch
1120657	COLISTINA SULFATO	25 g	241939-G-1
1120659	COLISTINA SULFATO	100 g	241939-J-1
1120660	COLISTINA SULFATO	250 g	241939-N-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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