



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 233429

Product:	COLISTIN SOLPHATE
Lot:	233429
Expiry date:	28/02/2027
Reference:	Cumple PhEur11.2
Synonyms:	Polimixina E sulfato.
Formule:	
Poids moléculaire:	g/mol

Assay	Result	Specification	
Composition (HPLC)	Conform		
Antimicrobial power	23027 UI/mg s.p.s	>= 19000 UI/mg s.p.s	
Residual solvent: Ethanol	< 5000 ppm	<= 5000 ppm	#
Nitrosamine impurities	Conform	Test PhEur	#
Elemental impurities	Conform	Test PhEur	#
Any impurity; not more than 4 >= 1.0%	1,3 % ; < 4	<= 2,5 % ; <= 4	
Impurity B	< 0,35 %	<= 4,0 %	
Polymyxin E1-I	0,64 %	<= 8,5 %	
Total impurities	4,7 %	<= 11,0 %	
Sulphates	16,9 %	16,0 - 18,0 %	
Poymyxin E2-I	0,73 %	<= 2,5 %	
Related substances (HPLC)	Conform		
Sum of polymyxins E4 and E2-Val	1,9 %	<= 3,0 %	
Sulphated ashes	0,17 %	<= 1,0 %	
Sum of polymyxins	93,5 %	>= 86,0 %	
Loss on drying	2,4 %	<= 3,5 %	
Polymyxin 2,3-dehidro E1	0,24 %	<= 1,5 %	
Identification	Conform (B,E)		
Polymyxin E1-7MOA	3,4 %	<= 5,0 %	
Polymyxin E3	2,8 %	<= 5,5 %	
pH	4,4	4,0 - 6,0	
Polymyxin E1-Nva	0,45 %	<= 4,5 %	
Organoleptic properties	Conform		
Polymyxin E6	1,0 %	Polymyxin E6	

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: 05/10/2023

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00433 LABORATORIUM OFICHEM B.V.

Manufacturer batch: 2302007.1224

Produit	Nom	Capacité	Lot
1120662	COLISTINA SULFATO	1 kg	233429-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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