

Certificate of Analysis

Product name: **Colistini sulfas**
Batch number / Weight: **23D12-B10-227813 / 100 G**
Analysed according to: **Ph.Eur.11.1**
Number of analysis / Inspection Code **23D12-B10 / INS-23-3870**
Reference Code / No.: **V01275 / 2110026.1224**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White to almost white hygroscopic powder	Conform		
Identification B	Conform	Conform		
Identification E	Conform	Conform		
pH	4,0 - 6,0	4,34		
Related substances	Conform	Conform		
Impurity B	<=4,0	<0,35	%	
Any impurity	<=2,5	1,56	%	
NMT 4 other imp.exceed 1,0%	conform	Conform		
Sum of impurities	<=11,0	7,42	%	
Sulphates	16,0 - 18,0 (dried substance)	16,62	%	
Loss on drying	<=3,5	0,9	%	
Sulphated ash	<= 1,0	0,24	%	
Polymyxin E1-I	<= 8,5	0,45	%	
Polymyxin E3	<= 5,5	2,86	%	
Polymyxin E1-7MOA	<= 5,0	3,83	%	
Polymyxin E6	<= 4,5	0,83	%	
Polymyxin E1-NvA	<= 4,5	<0,35	%	
Polymyxin E4 and E2-Val	<= 3,0	1,87	%	
Polymyxin E2-I	<= 2,5	0,85	%	
Polymyxin 2,3-dehydro E1	<= 1,5	<0,35	%	
Sum of polymyxins	>= 86,0	91,57	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Colistin sulphate	>=19000	23611	IU / mg	
Total aerobic microbial count (TA)	<=100	<10	CFU / g	
Total yeasts and moulds (TYMC)	<=10	<10	CFU/g	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL lab,CBMiA

Release:

Ewelina Gadzinowska

Qualified Person

16-06-2023

Expiration: 31-10-2025

Conclusion: APPROVED

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