

Certificate of Analysis

Product name: **Colistini sulfas**
Batch number / Weight: **21G20-B09-213545 / 5 G**
Analysed according to: **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White to almost white hygroscopic powder	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Identification D	Conform	Conform		
Identification E	Conform	Conform	%	
pH	4,0 - 6,0	4,32		
Related substances	Conform	Conform		
Impurity B	<=4,0	<0,35	%	
Any impurity	<=2,5	1,48	%	
Sum of impurities	<=11,0	7,78	%	
Sulphates	16,0 - 18,0 (dried substance)	16,79	%	
Loss on drying	<=3,5	0,09	%	
Sulphated ash	<= 1,0	0,03	%	
Polymyxin E1-I	<= 8,5	0,50	%	
Polymyxin E3	<= 5,5	3,27	%	
Polymyxin E1-7MOA	<= 5,0	3,66	%	
Polymyxin E6	<= 4,5	0,82	%	
Polymyxin E1-NvA	<= 4,5	<0,35	%	
Polymyxin E4 and E2-Val	<= 3,0	1,80	%	
Polymyxin E2-I	<= 2,5	0,86	%	
Polymyxin 2,3-dehydro E1	<= 1,5	<0,35	%	
Sum of polymyxins	>= 86,0	91,21	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Colistin sulphate	>=19000	19107,750	IU / mg	
Total aerobic microbial count (TAMC)	<=100	Conform	CFU / g	
Total yeasts and moulds (TYMC)	<=10	Conform	CFU/g	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:

Dominika Sołtysik
Qualified Person

21-10-2021

Expiration: 30-11-2023

Conclusion: APPROVED

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