

Certificate of Analysis

Product name: Polymyxini B sulfas
Batch number / Weight: 21K09-B10-216434 / 150 MG
Analysed according to: Ph. Eur.

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder	Conform		
Identification B	Conform	Conform		
Identification D	White	Conform		
pH	5,0 - 7,0	6,5		
Related substances	Conform	Conform		
Any impurity	<=3,0	1,32	%	
Total of impurities	<=17,0	2,93	%	
Sulphates	15,5 - 17,5	16,3	%	
Loss on drying	<=6,0	1,0	%	
Sulphated ash	<= 0,75	0,62	%	
Assay B1, B2, B3 and B1-1	>= 80,0	97,1	%m/m	
Assay Polymyxin B3	<= 6,0	2,1	%m/m	
Assay Polymyxin B1-1	<= 15,0	7,9	%m/m	
Total aerobic microbial count (TA)	<=100	Conform	CFU / g	
Total yeasts and moulds (TYMC)	<=10	Conform	CFU/g	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Polymyxin B	>=6000	8693	IU/mg	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Agnieszka Pszczółka
Qualified Person

26-02-2022

Expiration: 28-02-2026

Conclusion: APPROVED

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