

Certificate of Analysis

Product name: Polymyxini B sulfas
Batch number / Weight: 22K22-B02-226814 / 600 MG
Analysed according to: Ph.Eur. 01/2016:0019
Number of analysis / Inspection Code 22K22-B02 / INS-22-9983
Reference Code / No.: V01639 / 220955

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, hygroscopic powder	Conform		
Identification B	Conform	Conform		
Identification D	White	Conform		
pH	5,0 - 7,0	6,15		
Related substances	Conform	Conform		
Any impurity	<=3,0	2,50	%	
Total of impurities	<=17,0	7,18	%	
Sulphates	15,5 - 17,5	15,89	%	
Loss on drying	<=6,0	0,99	%	
Sulphated ash	<= 0,75	0,100	%	
Assay B1, B2, B3 and B1-1	>= 80,0	92,82	%m/m	
Assay Polymyxin B3	<= 6,0	2,34	%m/m	
Assay Polymyxin B1-1	<= 15,0	7,75	%m/m	
Total aerobic microbial count (TA)	<=100	<10	CFU / g	
Total yeasts and moulds (TYMC)	<=10	<1	CFU/g	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Polymyxin B	>=6500	6560,219	IU/mg	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Acetone	<= 5000	<5000	ppm	

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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 FAPL/Eurofins/CBM

Release:

Agnieszka Pszczółka

Qualified Person

30-01-2023

Expiration: 31-10-2027

Conclusion: APPROVED

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