

Certificate of Analysis

Product name: Polymyxini B sulfas

Batch number / Weight: 23D28-B11-234313 / 600 MG

Analysed according to: Ph.Eur.11.2

Number of analysis / Inspection Code 23D28-B11 / INS-23-5277

Reference Code / No.: V01639 / 221277

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	6,08		
Related substances	Conform	Conform		
Any impurity	<=3,0	2,57	%	DP
Total of impurities	<=17,0	6,62	%	
Sulphates	15,5 - 17,5	16,45	%	
Loss on drying	<=6,0	0,6	%	
Sulphated ash	<= 0,75	0,10	%	
Assay B1, B2, B3 and B1-1	>= 80,0	93,38	%m/m	
Assay Polymyxin B3	<= 6,0	2,22	%m/m	
Assay Polymyxin B1-1	<= 15,0	7,24	%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
Aktivität Polymyxin B	>=6500	7896	IU/mg	
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:

Agnieszka Pszczółka

Qualified Person

11-10-2023

Expiration: 31-01-2028

Conclusion: APPROVED

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