

Certificate of Analysis

Productname: Polymyxini B sulfas
Number of analysis/Inspection Code: 1 / KEUR-179554B
Batchnumber: 19A23-B01-363960
Reference code / No.: 3096 / 180931
Analysed according to: PH.EUR9.6+

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder	Conform		Hygroscopic
Identification B	Conform	Conform		HPLC
Identification D	White	Conform		Sulphate
pH	5,0 - 7,0	5,5		2%m/V
Specific optical rotation	-78 - -90	-81	°	2% m/V; dried
Related substances	Conform	Conform		HPLC
Any impurity	<=3,0	<3,0	%	
Total of impurities	<=17,0	3,8	%	
Sulphates	15,5 - 17,5	15,6	%	Dried
Loss on drying	<=6,0	2,2	%	3 h 60°C in vacuo
Sulphated ash	<= 0,75	0,30	%	
Assay B1, B2, B3 and B1-I	>= 80,0	94,8	%m/m	Dried
Assay Polymyxin B3	<= 6,0	2,4	%m/m	Dried
Assay Polymyxin B1-I	<= 15,0	8,0	%m/m	Dried
Total aerobic microbial count (TAMC)	<=10 ²	Conform	CFU / g	
Total yeasts and moulds (TYMC)	<=10 ¹	Conform	CFU / g	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Polymyxin B	>=6500	8034	IU/mg	Data producer, USP method
Assay Polymyxin B		7857	IU/mg	As is; no dried; data producer; USP meth.
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Eurofins.

Release:
 dr. M.J. Vincenten - van Maanen
 Pharmacist - Qualified Person

01/14/20

Expiration: 11-2023

Conclusion: APPROVED

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