

Certificate of Analysis

Productname: Polymyxini B sulfas
Number of analysis/Inspection Code: 3 / KEUR-182294B
Batchnumber: 19I11-F01-369168
Reference code / No.: 3096 / 190528
Analysed according to: PHEUR10.0+

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	6,2		2%m/V
Related substances	Conform	Conform		HPLC
Any impurity	<=3,0	2,9	%	
Total of impurities	<=17,0	7,6	%	
Sulphates	15,5 - 17,5	16,6	%	Dried
Loss on drying	<=6,0	5,1	%	3 h 60°C in vacuo
Sulphated ash	<= 0,75	0,36	%	
Assay B1, B2, B3 and B1-I	>= 80,0	91,5	%m/m	Dried
Assay Polymyxin B3	<= 6,0	2,4	%m/m	Dried
Assay Polymyxin B1-I	<= 15,0	7,4	%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	7890	IU/mg	Dried
Assay Polymyxin B		7488	IU/mg	As is, no dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
Wai Lung Chung
Pharmacist - Qualified Person

04/28/20

Expiration: 06-2024

Conclusion: APPROVED

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