

QUALITY CONTROL

Caesar & Loretz GmbH

Herderstr. 31

40721 Hilden

Phone: 02103/49940

Certificate of analysis

Article	5530	Polymyxin B sulfat, API (mikrobielle Herkunft)	
Synonym		Polymyxini B sulfas	
Synonym		Polymyxin B sulfate, API	
Batch	22003109		
Specification	Ph.Eur.10.1		
Production date	08.2022	Retest date	08.2024

Test	Specification	Result
Characters	According to specification	Complies
Appearance	According to specification	Complies
Solubility	According to specification	Complies
Identification	According to specification	Complies
HPLC	According to specification	Complies
D	According to specification	Complies
Tests	According to specification	Complies
pH-Value	5,0 ... 7,0	6,0
Composition	According to specification	Complies
Assay (total Polymycine)	Min. 80,0 %	96,0 %
Assay (Polymycine B3)	Max. 6,0 %	2,4 %
Assay (Polymycine B1-I)	Max. 15,0 %	7,9 %
Related substances	According to specification	Complies
Any impurity	Max. 3,0 %	2,7 %
Total of all impurities	Max. 17,0 %	4,0 %
Sulphates	15,5 ... 17,5 %	16,3 %
Loss on drying	Max. 6,0 %	3,8 %
Sulphated ash	Max. 0,75 %	0,00 %
Content	Min. 6500 I.E./mg	7703 I.E./mg
Correction factor weighing (f, NRF)	1,000	1,134
Complies specification		Yes

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Release date	16.11.2022	Released by	Frau Dr. Haßel, QP, LQK
Manufacturer	BIOTIKA A.S.		
Manufacturer batch	220635		
Manufacturer street	Slovenska Lupca 566		
Manufacturer city	976 13 Slovenska Lupca		
Manufacturer country	Slowakei		

GMP-compliant production and testing of the active pharmaceutical ingredients

Results marked with # were taken from the manufacturer's certificate.

The batch 22003109 complies specification.

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