

POLYMYXINI B SULFAS 150 mg

Lot No.: 24C11-APR24047

Autorisation :	1890R05435	Date Of Analysis :	18/01/2024
Analytical Reference :	Ph. Eur. 11.4 [04/2019:0203] Corr. 10.3	Production Number :	120324-GS23134
CNK :	3490-752	Expiry Date :	01/2028

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	White or almost white, hygroscopic powder.	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification B	The chromatogram obtained with the test solution shows zones corresponding to those in the chromatograms obtained with reference solutions (a), (b) and (c), but shows no zone corresponding to that in the chromatogram obtained with reference solution (d); the chromatogram obtained with the test solution also shows a zone with a very low RF value (2,4-diaminobutyric acid).	Complies
Identification D	It gives reaction (a) of sulfates.	Complies
TESTS	SPECIFICATION	RESULT
pH	5.0 to 7.0	5.9
Composition		
Polymyxin B1-I	≤ 15.0%	6.6%
Polymyxin B3	≤ 6.0%	0.4%
Sum of polymyxins B1, B2, B3 and B1-I	≥ 80.0%	95.6%
Related substances		
Any impurity	≤ 3.0%	1) 1.1% 2) 0.8% 3) 0.7% 4) 0.8%
Total	≤ 17.0%	3.3%
Sulfate	15.5% to 17.5% (dried substance)	15.6%
Loss on drying	≤ 6.0%	1.0%
Sulfated ash	≤ 0.75%	0.44%
ASSAY	SPECIFICATION	RESULT
Microbiological assay of antibiotics: Potency	≥ 6500 IU/mg (dried substance)	7122 IU/mg

Manufacturer identification code: S/GS/206

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: