BIOTIKA

Biotika a.s., Slovenská Ľupča 566, 976 13 Slovenská Ľupča, Slovak Republic, Tel.: +421 48 4368153 e-mail: cervenakova@biotika.sk

CERTIFICATE OF ANALYSIS: 766/2019

POLYMYXIN B SULFATE non-sterile, micronized

Batch No.: 1904103
Manufacture date: 01.2019
Re-test date: 01.2024

Tests	Specifications	Results
Characters	white or almost white, hygroscopic powder	complies
Identification		
B. HPLC *EP*	should comply	complies
D. Sulfate test *EP*	should comply	complies
A. HPLC *USP*	should comply	complies
B. Color reaction *USP*	should comply	complies
C. Test for Sulfate *USP*	should comply	complies
pH *EP*	5.0 to 7.0	6.1
pH (0.5 % solution) *USP*	5.0 to 7.5	6.0
Related substances *EP*		
Any impurity	maximum 3.0 %	2.4 %
Total	maximum 17.0 %	6.8 %
Organic Impurities *USP*		
Any individual impurity	not more than 3.0 %	2.5 %
Total impurities	not more than 17.0 %	5.6 %
Residual solvents *EP*		
Acetone	not more than 0.5 %	0.01 %
Sulfate (dried substance) *EP*	15.5 % to 17.5 %	16.4 %
Loss on drying		
EP	maximum 6.0 %	1.8 %
USP	not more than 7.0 %	1.8 %
Sulfated ash *EP*	maximum 0.75 %	0.24 %
Residue on ignition *USP*	not more than 5.0 %	0.2 %
Microbiological purity *EP*		
Total Aerobic Microbial Count	maximum 10^2 CFU/g	0 CFU/g
Total Yeasts and Moulds Count	maximum 10 CFU/g	0 CFU/g
Bile tolerant gram negative bacteria	absence/g	complies
Pseudomonas aeruginosa	absence/g	complies
Staphylococcus aureus	absence/g	complies
Pathogenic anaerobic micro-organisms	absence/g	complies
Enterococcus	absence/g	complies
Particle size *IN-HOUSE METHOD*	not less than 99.0 % ≤ 20 µm by vol. not less than 90.0 % ≤ 15 µm by vol. not less than 75.0 % ≤ 10 µm by vol. not less than 35.0 % ≤ 5 µm by vol.	99.0 % : ≤ 17 µm 90.0 % : ≤ 11 µm 75.0 % : ≤ 8 µm 35.0 % : ≤ 4 µm
Composition *EP*		
Polymyxin B1-I	maximum 15.0 %	7.7 %
Polymyxin B3	maximum 6.0 %	2.4 %
Sum of polymyxins B1, B2, B3 and B1-I	minimum 80.0 %	93.3 %
Composition of Polymyxins (dried substance) *USP*		
Sum of polymyxins B1, B2, B3 and B1-I	not less than 80.0 %	97.3 %
Polymyxin B3	not more than 6.0 %	2.2 %
Polymyxin B1-I	not more than 15.0 %	8.0 %
Assay (dried substance) *EP*	minimum 6500 IU/mg	8062 IU/mg
Assay (microbial) *USP*	not less than 6000 Polymyxin B Units/mg calculated on dried basis	8062 Polymyxin B Units/mg

Product is in conformity with the specifications of EP 9 and USP 42.

Date: December 03, 2019

Biotika a.s. -22-
sídlo: 976 13 Slovenská Ľupča 566,
Slovenská republika
IČO: 31 561 900, IČ DPH SK2020452412
Obch. reg. Okr. súdu B. Bystrica, vl. 65/S, odd: Sa

Ing. Jana Červenáková
Quality Director, Qualified Person