METAPHARMACEUTICAL

N DE LOTE:
0191123

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23/11/2023

Certificate of analysis

Product:	Colistin sulfate
Batch number:	**2302050.1224**
Manufacturing date:	Feb-2023
Retest date:	Feb-2027
Storage claim	N/a

Parameter	Method	Specification	Results
Characters			
Appearance	Visual	White or almost white hygroscopic powder	Almost white hygroscopic powder
Identification *First identification: B, E*			
Identification B	EP 0320	Relative retention time of polymyxin E1 and polymyxin E2 are conform reference	Conform reference
Identification E	EP 2.3.1 (a)	Reaction on sulfates is positive	Positive
Tests			
pH	EP 2.2.3	4.0 – 6.0	4.1
Composition	HPLC EP 2.2.29	Polymyxin E1-I ≤ 8.5 area %	< 0.4 %
		Polymyxin E3 ≤ 5.5 area %	2.9 %
		Polymyxin E1-7MOA ≤ 5.0 area %	3.3 %
		Polymyxin E6 ≤ 4.5 area %	1.1 %
		Polymyxin E1-Nva ≤ 4.5 area %	< 0.4 %
		Sum of polymyxins E4 and E2-Val ≤ 3.0 area %	1.9 %
		Polymyxin E2-I ≤ 2.5 area %	0.7 %
		Polymyxin 2.3-dehydro E1 ≤ 1.5 area %	< 0.4 %
		Sum of polymyxins E1, E2, E3, E4, E6, E1-7MOA, E1-I, E1-Nva, E2-I, E2-Val and 2.3-dehydro E1 ≥ 86.0 area %	89.5 %
Related substance	HPLC EP 2.2.29	Impurity B ≤ 4.0 area %	0.2 %
		Any other impurity: each other impurity ≤ 2.5 area % but in total not more than 4 impurities ≥ 1.0 area %	2.0 % Complies
		Total impurities ≤ 11.0 area %	8.5 %

Quality Control

L. Boxem, BSc 07 APR 2023

Quality Assurance

11 APR 2023

J. Furda, BSc

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Parameter	Method	Specification	Results
Sulfate (on dried substance)	EP 0320	16.0 – 18.0 %	16.4 %
Loss on drying	EP 2.2.32	≤ 3.5 %	2.2 %
Sulfated ash	EP 2.4.14	≤ 1.0 %	0.3 %
Residual solvents	Internal method	Ethanol ≤ 5000 ppm	35 ppm
Assay			
Microbiological assay (on dried substance)	EP 2.7.2	≥ 19000 IU/mg	23529 IU/mg

This lot complies with the current version of Ph. Eur. of colistin sulfate and company monograph.
This batch of product has been manufactured, including packaging / labelling and quality control in full compliance with the GMP requirements.

Quality Control

L. Boxem, BSc 07 APR 2023

Quality Assurance

J. Furda, BSc 11 APR 2023