

Certificate of analysis

Product:	Colistin sulfate
Batch number:	2110016.1224
Manufacturing date:	Oct-2021
Retest date:	Oct-2024
Storage claim	N/a

Parameter	Method	Specification	Results
Characters			
Appearance	Visual	White or almost white hygroscopic powder	Almost white hygroscopic powder
Identification <i>First identification: B, E</i>			
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	4.3
Composition	HPLC EP 2.2.29	Polymyxin E1-I ≤ 8.5 area %	0.4 %
		Polymyxin E3 ≤ 5.5 area %	2.6 %
		Polymyxin E1-7MOA ≤ 5.0 area %	3.7 %
		Polymyxin E6 ≤ 4.5 area %	0.8 %
		Polymyxin E1-Nva ≤ 4.5 area %	< 0.4 %
		Sum of polymyxines E4 and E2-Val ≤ 3.0 area %	1.7 %
		Polymyxin E2-I ≤ 2.5 area %	0.7 %
		Polymyxin 2.3-dehydro E1 ≤ 1.5 area %	< 0.4 %
		Sum of polymyxines E1, E2, E3, E4, E6, E1-7MOA, E1-I, E1-Nva, E2-I, E2-Val and 2.3-dehydro E1 ≥ 86.0 area %	92.6 %
Related substance	HPLC EP 2.2.29	Impurity B ≤ 4.0 area %	< 0.4 %
		Any other impurity: each other impurity ≤ 2.5 area % but in total not more than 4 impurities ≥ 1.0 area %	1.2 % Complies
		Total impurities ≤ 11.0 area %	4.4 %

Quality Control



15 NOV 2021

R. Vree Egberts, BASc

Quality Assurance



18 NOV 2021

J. Fijda, BSc

Heembadweg 5, 9561 CZ, Ter Apel, The Netherlands		T: +31 599 583 433	F: +31 599 582 734	E: info@ofichem.com	
Documentcode:	COA-0005	Version:	1.0	Page:	1 / 2

Parameter	Method	Specification	Results
Sulfate	EP 0320	16.0 – 18.0 %	16.2 %
Loss on drying	EP 2.2.32	≤ 3.5 %	2.6 %
Sulfated ash	EP 2.4.14	≤ 1.0 %	0.2 %
Residual solvents	Internal method	Ethanol ≤ 5000 ppm	< 252 ppm
Assay			
Microbiological assay	EP 2.7.2	≥ 19000 IU/mg	24466 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



15 NOV 2021

R. Vree Egberts, BSc

Quality Assurance



18 NOV 2021

J. Furda, BSc

Heembadweg 5, 9561 CZ, Ter Apel, The Netherlands		T: +31 599 583 433	F: +31 599 582 734	E: info@ofichem.com	
Documentcode:	COA-0005	Version:	1.0	Page:	2 / 2