



TECHNICAL DATA SHEET

002210-TDS-ENG-2025

COLISTINA SULFATO (EUR. PH.)		
DESCRIPTION DCI: COLISTIN SULFATE		DESCRIPTION DOE: COLISTINA SULFATO
CAS Nº: 1264-72-8	EC Nº: 215-034-3	AEMPS CODE: 689SU
MOL. WEIGHT: ---	MOL. FORMULA: ---	ARTICLE CODE: 002210

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, hygroscopic powder
Solubility	Freely soluble in water, practically insoluble in acetone and in ethanol (96 %)
Identification B	Complies
Identification E	Complies
pH	4.0 - 6.0
Composition	
Polymyxin E1-I	=< 8.5 %
Polymyxin E3	=< 5.5 %
Polymyxin E1-7MOA	=< 5.0 %
Polymyxin E6	=< 4.5 %
Polymyxin E1-Nva	=< 4.5 %
Sum polymyxins E4 and E2-Val	=< 3.0 %
Polymyxin E2-I	=< 2.5 %
Polymyxin 2,3-dehydro E1	=< 1.5 %
Sum of Polymyxins	=> 86.0 %
Related substances	
Impurity B	=< 4.0 %
Any other impurity	
Each impurity	=< 2.5 %
Not more 4 impurities > 1.0 %	Complies
Total impurities	=< 11.0 %
Sulfates	16.0 - 18.0 %
Loss on drying	=< 3.5 %
Sulfated ash	=< 1.0 %
Assay	=> 19000 IU/mg
Microbiological control	
TAMC	=< 1000 CFU/g
TYMC	=< 100 CFU/g
S. Aureus	Absence/1g
E. Coli	Absence/1g
P. Aeruginosa	Absence/1g
C. Albicans	Absence/1g
Salmonella	Absence/1g

COMPLIES WITH

European Pharmacopoeia 11.1



TECHNICAL DATA SHEET

002210-TDS-ENG-2025

COLISTINA SULFATO (EUR. PH.)		
DESCRIPTION DCI: COLISTIN SULFATE		DESCRIPTION DOE: COLISTINA SULFATO
CAS Nº: 1264-72-8	EC Nº: 215-034-3	AEMPS CODE: 689SU
MOL. WEIGHT: ---	MOL. FORMULA: ---	ARTICLE CODE: 002210

STORAGE

Keep tightly closed, in a cool and dry place.

REMARKS

Colistin Sulfate is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.