METAPHARMACEUTICAL IND SL
Josep Plà, 163, 2n 5a / Tel. 933 089 976 / info@metapharmaceutical.com

COLISTINA SULFATO (EUR. PH.)

PRODUCT CODE: 002210	CAS Nº: 1264-72-8	ANALYSIS Nº: 069/25	
MANUFACTURER BATCH:	CS-20241204	CERTIFICATE ID:	45.572
SUPPLIER BATCH:	----	MANUFACTURING DATE:	07/12/2024
METAPH BATCH:	0210325	EXPIRY DATE:	06/12/2027

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, hygroscopic powder	Almost white, hygroscopic powder
Identification B	Complies	Complies
Identification E	Complies	Complies
pH	4.0 - 6.0	5.0
Composition		
Polymyxin E1-I	=< 8.5 %	0.4 %
Polymyxin E3	=< 5.5 %	3.8 %
Polymyxin E1-7MOA	=< 5.0 %	3.6 %
Polymyxin E6	=< 4.5 %	0.7 %
Polymyxin E1-Nva	=< 4.5 %	< 0.35 %
Sum polymyxins E4 and E2-Val	=< 3.0 %	2.2 %
Polymyxin E2-I	=< 2.5 %	0.6 %
Polymyxin 2,3-dehydro E1	=< 1.5 %	0.9 %
Sum of Polymyxins	=> 86.0 %	95.2 %
Related substances		
Impurity B	=< 4.0 %	< 0.35 %
Any other impurity		
Each impurity	=< 2.5 %	< 2.5 % (#)
Not more 4 impurities > 1.0 %	Complies	Complies
Total impurities	=< 11.0 %	4.2 %
Sulfates	16.0 - 18.0 %	18.0 %
Loss on drying	=< 3.5 %	0.2 %
Sulfated ash	=< 1.0 %	0.2 %
Assay	=> 19000 IU/mg	22196 IU/mg
Microbiological control		
TAMC	=< 1000 CFU/g	=< 10 CFU/g
TYMC	=< 100 CFU/g	=< 10 CFU/g
S. Aureus	Absence/1g	Absence/1g
E. Coli	Absence/1g	Absence/1g
P. Aeruginosa	Absence/1g	Absence/1g
C. Albicans	Absence/1g	Absence/1g
Salmonella	Absence/1g	Absence/1g

COMPLIES WITH

European Pharmacopoeia 11.1

REMARKS

(#) Impurities detailed underneath:
RT (4.19 min) = 1.05 %
RT (9.84 min) = 1.19 %

Analysis date: 24/04/2025
Signature: Cristina Borrell Olea (QA/QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000349
H. G. (WAICOME PHARMA)
No. 138 YuWu Road
XinMin Town
408302 Chonqing

METAPHARMACEUTICAL IND SL
Josep Plà, 163, 2n 5a / Tel. 933 089 976 / info@metapharmaceutical.com

COLISTINA SULFATO (EUR. PH.)

PRODUCT CODE: 002210	CAS Nº: 1264-72-8	ANALYSIS Nº: 069/25	
MANUFACTURER BATCH:	CS-20241204	CERTIFICATE ID:	45.572
SUPPLIER BATCH:	----	MANUFACTURING DATE:	07/12/2024
METAPH BATCH:	0210325	EXPIRY DATE:	06/12/2027

Product fully analyzed within the EU, in compliance with the currents regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

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

All data controlled by Metapharmaceutical Industrial SL.

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.

STORAGE

Keep tightly closed, in a cool and dry place.

Analysis date: 24/04/2025
Signature: Cristina Borrell Olea (QA/QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000349
H. G. (WAICOME PHARMA)
No. 138 YuWu Road
XinMin Town
408302 Chonqing