

## Certificate of Analysis

**Product name:** Colistini sulfas  
**Batch number / Weight:** 21G20-B07-215432 / 5 G  
**Analysed according to:** Ph. Eur.

| Tests                                | Requirement                                  | Result    | Unit    | Standard remark |
|--------------------------------------|--|-----------|---------|-----------------|
| Appearance                           | White to almost white hygroscopic powder     | Conform   |         |                 |
| Identification B                     | Conform                                      | Conform   |         |                 |
| Identification C                     | Conform                                      | Conform   |         |                 |
| Identification D                     | Conform                                      | Conform   |         |                 |
| Identification E                     | Conform                                      | Conform   | %       |                 |
| pH                                   | 4,0 - 6,0                                    | 4,08      |         |                 |
| Related substances                   | Conform                                      | Conform   |         |                 |
| Impurity B                           | <=4,0  | <0,35     | %       |                 |
| Any impurity                         | <=2,5  | 1,50      | %       |                 |
| Sum of impurities                    | <=11,0                                       | 7,89      | %       |                 |
| Sulphates                            | 16,0 - 18,0 (dried substance)                | 16,74     | %       |                 |
| Loss on drying                       | <=3,5  | 0,17      | %       |                 |
| Sulphated ash                        | <= 1,0                                       | 0,03      | %       |                 |
| Polymyxin E1-I                       | <= 8,5                                       | 0,51      | %       |                 |
| Polymyxin E3                         | <= 5,5                                       | 3,01      | %       |                 |
| Polymyxin E1-7MOA                    | <= 5,0                                       | 3,64      | %       |                 |
| Polymyxin E6                         | <= 4,5                                       | 0,79      | %       |                 |
| Polymyxin E1-NvA                     | <= 4,5                                       | <0,35     | %       |                 |
| Polymyxin E4 and E2-Val              | <= 3,0                                       | 1,78      | %       |                 |
| Polymyxin E2-I                       | <= 2,5                                       | 0,85      | %       |                 |
| Polymyxin 2,3-dehydro E1             | <= 1,5                                       | <0,35     | %       |                 |
| Sum of polymyxins                    | >= 86,0                                      | 90,77     | %       |                 |
| Metallic residues                    | CHMP/ICH/353369/2013                         | Conform   |         | Data producer   |
| Residual solvents                    | CPMP/ICH/82 260/06                           | Conform   |         | Data producer   |
| Assay Colistin sulphate              | >=19000                                      | 19063,214 | IU / mg |                 |
| Total aerobic microbial count (TAMC) | <=100  | Conform   | CFU / g |                 |
| Total yeasts and moulds (TYMC)       | <=10   | Conform   | CFU/g   |                 |
| TSE/BSE-statement:                   | No contamination with TSE/BSE-risk materials | Conform   |         | Data producer   |

Analysis performed by the authorized lab.

Release:

Agnieszka Pszczółka  
Qualified Person

27-08-2021

Expiration: 30-11-2023

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.