

Certificate of Analysis

Product name: Colistini sulfas
Batch number: 20F18-B04-201840
Base unit: 5g
Expiration date: 30.09.2021
Quality: Ph. Eur.
Manufacturing date: 07.07.2020
Inspection report no.: INS-20-03019
IIN: 100346-114-91

| Description | Claim | Result | Unit | Laboratory |
|--|---|-----------------------|--------|---------------|
| Appearance | White to almost white hygroscopic powder | conform | | |
| Identification B | acc. to Ph. Eur. | conform | | |
| Identification E | acc. to Ph. Eur. | conform | | |
| pH | 4,0 – 6,0 | 4,48 | | |
| Related substances | - impurity B: max. 4,0% - any impurity: max. 2,5% - sum of impurities: max. 11,0% | <0,35 1,45 5,37 | % | |
| Sulfates | 16,0 – 18,0 | 17,50 | % | |
| Loss on drying | max. 3,5% | 1,8 | % | data producer |
| Sulfated ash | max. 1,0% | 0,15 | % | |
| Polymixin E1-I | max. 8,5% | 0,38 | % | |
| Polymixin E3 | max. 5,5% | 3,66 | % | |
| Polymixin E1-7MOA | max. 5,0% | 3,75 | % | |
| Polymixin E6 | max. 4,5% | 0,75 | % | |
| Polymixin E1-Nva | max. 4,5% | 0 | % | |
| Sum of polymyxins E4 and E2-Val | max. 3,0% | 1,85 | % | |
| Polymixin E2-I | max. 2,5% | 0,91 | % | |
| Polymixin 2,3-dehydro E1 | max. 1,5% | <0,35 | % | |
| Sum of polymyxins E1,E2,E3,E4,E6, E1-7MOA,E1-I,E1-Nva,E2-I,E2-Val and 2,3-dehydro E1 | min. 86,0% | 93,46 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | conform | | data producer |
| Residual solvents | CPMP/ICH/82 260/06 | conform | | data producer |
| Assay Colistin sulphate | Min. 19 000 IU/ mg | 22 102 | IU/ mg | data producer |
| Microbial contamination | -TAMC: max. 100 CFU/g -TYMC: max. 10 CFU/g | conform conform | CFU/g | |
| TSE/BSE-statement | No contamination with TSE/BSE-risk materials | conform | | data producer |

Analysis performed by the laboratory: Fagron Poland

Release:
Ewelina Gadzinowska, Qualified Person
Date of releasing: 23.07.2020



Fagron sp. z o.o.
Ewelina Gadzinowska
osoba wykwalifikowana
qualified person

Conclusion: Approved