



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 233429

| | |
|-------------------|-----------------------|
| Product: | COLISTIN SOLPHATE |
| Lot: | 233429 |
| Expiry date: | 28/02/2027 |
| Reference: | Cumple PhEur11.2 |
| Synonyms: | Polimixina E sulfato. |
| Formula: | |
| Molecular weight: | g/mol |

| Assay | Result | Specification | |
|---------------------------------------|-------------------|----------------------|---|
| Composition (HPLC) | Conform | | |
| Antimicrobial power | 23027 UI/mg s.p.s | >= 19000 UI/mg s.p.s | |
| Residual solvent: Ethanol | < 5000 ppm | <= 5000 ppm | # |
| Nitrosamine impurities | Conform | Test PhEur | # |
| Elemental impurities | Conform | Test PhEur | # |
| Any impurity; not more than 4 >= 1.0% | 1,3 % ; < 4 | <= 2,5 % ; <= 4 | |
| Impurity B | < 0,35 % | <= 4,0 % | |
| Polymyxin E1-I | 0,64 % | <= 8,5 % | |
| Total impurities | 4,7 % | <= 11,0 % | |
| Sulphates | 16,9 % | 16,0 - 18,0 % | |
| Poymyxin E2-I | 0,73 % | <= 2,5 % | |
| Related substances (HPLC) | Conform | | |
| Sum of polymyxins E4 and E2-Val | 1,9 % | <= 3,0 % | |
| Sulphated ashes | 0,17 % | <= 1,0 % | |
| Sum of polymyxins | 93,5 % | >= 86,0 % | |
| Loss on drying | 2,4 % | <= 3,5 % | |
| Polymyxin 2,3-dehidro E1 | 0,24 % | <= 1,5 % | |
| Identification | Conform (B,E) | | |
| Polymyxin E1-7MOA | 3,4 % | <= 5,0 % | |
| Polymyxin E3 | 2,8 % | <= 5,5 % | |
| pH | 4,4 | 4,0 - 6,0 | |
| Polymyxin E1-Nva | 0,45 % | <= 4,5 % | |
| Organoleptic properties | Conform | | |
| Polymyxin E6 | 1,0 % | Polymyxin E6 | |

Organoleptic characteristics: White or almost white, hygroscopic powder. Freely soluble in water, practically insoluble in acetone and in ethanol (96 per cent).

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 05/10/2023

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00433 LABORATORIUM OFICHEM B.V.

Manufacturer batch: 2302007.1224

| Product | Name | Capacity | Batch |
|---------|-------------------|----------|------------|
| 1120662 | COLISTINA SULFATO | 1 kg | 233429-P-1 |

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

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