



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 230158

| | |
|--------------------|--|
| Product: | NYSTATIN |
| Lot: | 230158 |
| Expiry date: | 30/09/2025 |
| Reference: | Cumple PhEur11.0 |
| Synonyms: | |
| Formule: | C ₄₇ H ₇₅ NO ₁₇ |
| Poids moléculaire: | 926,1 g/mol |

| Assay | Result | Specification | |
|----------------------------|------------------|----------------------|---|
| Nystatin A1 | 93,0 % | >= 85,0 % | |
| Any other compound | 1,9 % | <= 4,0 % | |
| Organoleptic properties | Conform | | |
| Absorbance | 0,80 | >= 0,60 | = |
| Residual solvent: Methanol | < 3000 ppm | <= 3000 ppm | # |
| Identification | Conform (B,E) | | |
| Residual solvent: acetone | < 5000 ppm | <= 5000 ppm | # |
| Loss on drying | 3,8 % | <= 5,0 % | |
| Composition (HPLC) | Conform | | |
| Elemental impurities | Conform | Test PhEur | # |
| Sulphated ashes | 0,85 % | <= 3,5 % | = |
| Antimicrobial power | 6349 UI/mg s.p.s | >= 5000 UI/mg s.p.s. | |

Organoleptic characteristics: Yellow or slightly brownish powder, hygroscopic. Practically insoluble in water, freely soluble in dimethylformamide and in dimethyl sulfoxide, slightly soluble in methanol, practically insoluble in alcohol.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 10/02/2023

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00050 S.C. ANTIBIOTICE S.A.

Manufacturer batch: 4012127

| Produit | Nom | Capacité | Lot |
|---------|-----------|----------|------------|
| 1162608 | NISTATINA | 10 g | 230158-F-1 |
| 1162608 | NISTATINA | 10 g | 230158-F-2 |
| 1162608 | NISTATINA | 10 g | 230158-F-3 |
| 1162608 | NISTATINA | 10 g | 230158-F-4 |

| | | | |
|---------|----------------------|-------|------------|
| 1162609 | NISTATINA | 25 g | 230158-G-1 |
| 1162609 | NISTATINA | 25 g | 230158-G-2 |
| 1162609 | NISTATINA | 25 g | 230158-G-3 |
| 1162609 | NISTATINA | 25 g | 230158-G-4 |
| 1162615 | NISTATINA | 1 kg | 230158-P-1 |
| 1162615 | NISTATINA | 1 kg | 230158-P-2 |
| 1162615 | NISTATINA | 1 kg | 230158-P-3 |
| 1162615 | NISTATINA | 1 kg | 230158-P-4 |
| 1200211 | NISTATINA (INACTIVO) | 5 g | 230158-E-1 |
| 1200211 | NISTATINA (INACTIVO) | 5 g | 230158-E-2 |
| 1200213 | NISTATINA | 100 g | 230158-J-1 |
| 1200213 | NISTATINA | 100 g | 230158-J-2 |
| 1200213 | NISTATINA | 100 g | 230158-J-3 |
| 1200213 | NISTATINA | 100 g | 230158-J-4 |

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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