



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 240164

| | |
|--------------------|------------------|
| Product: | NYSTATIN |
| Lot: | 240164 |
| Expiry date: | 31/12/2026 |
| Reference: | Cumple PhEur11.3 |
| Synonyms: | |
| Formule: | C47H75NO17 |
| Poids moléculaire: | 926,1 g/mol |

| Assay | Result | Specification | |
|-----------------------------|-------------------|--------------------------|---|
| Identification | Conform (B,E) | | |
| Organoleptic properties | Conform | | |
| Absorbance | 0,85 | $\geq 0,60$ | |
| Composition (HPLC) | Conform | | |
| Elemental impurities | Conform | Test PhEur | # |
| Loss on drying | 2,5 % | $\leq 5,0 \%$ | |
| Sulphated ashes | 1,4 % | $\leq 3,5 \%$ | |
| Antimicrobial power | 6541 UI/mg s.p.s. | ≥ 5000 UI/mg s.p.s. | |
| Nystatin A1 | 93,3 % | $\geq 85,0 \%$ | |
| Any other compound | 2,9 % | $\leq 4,0 \%$ | |
| Residual solvent: Methanol | < 3000 ppm | ≤ 3000 ppm | # |
| Residual solvent: acetone | < 5000 ppm | ≤ 5000 ppm | # |
| Residual solvent: 1-Butanol | < 5000 ppm | ≤ 5000 ppm | # |
| Nitrosamine impurities | Conform | Test PhEur | # |

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: 06/02/2024

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F01035

Manufacturer batch: 00100124

| Produit | Nom | Capacité | Lot |
|---------|-----------|----------|------------|
| 1162608 | NISTATINA | 10 g | 240164-F-1 |
| 1162608 | NISTATINA | 10 g | 240164-F-2 |

| | | | |
|---------|----------------------|-------|------------|
| 1162609 | NISTATINA | 25 g | 240164-G-1 |
| 1162609 | NISTATINA | 25 g | 240164-G-2 |
| 1162615 | NISTATINA | 1 kg | 240164-P-1 |
| 1162615 | NISTATINA | 1 kg | 240164-P-2 |
| 1200211 | NISTATINA (INACTIVO) | 5 g | 240164-E-1 |
| 1200211 | NISTATINA (INACTIVO) | 5 g | 240164-E-2 |
| 1200213 | NISTATINA | 100 g | 240164-J-1 |
| 1200213 | NISTATINA | 100 g | 240164-J-2 |

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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