**Antibiotice**
Science and soul

FAGRON IBERICA, S.A.U
Corresponde al lote de Fagron:
150-23-B02
Director Técnico

# CERTIFICATE OF ANALYSIS No. 3873

| Product | NYSTATIN | |
|---|---|---|
| Analysis Record: 27.05.2015 | Batch No. 401 8291 | Quantity: 83000 g |
| We S.C. ANTIBIOTICE S.A., as a manufacturer of Nystatin hereby certify that this batch has been produced by us in full compliance with the Certificate of GMP Compliance of Manufacturer No. 025/2013/RO issued by NAMMD, valid starting with 21.06.2013. This batch has been manufactured, packaged and tested in accordance with EU GMP Guideline volume 4 part II (ICHQ7). | | Mfg. Date 05.2015<br>Exp. Date 05.2018 |

| ANALYSES PERFORMED | CONDITIONS | RESULTS |
|---|---|---|
| Appearance | Yellow or slightly brownish powder, hygroscopic.<br>Yellow to light tan powder, having an odor suggestive of cereals. Is hygroscopic, and is affected by long exposure to light, heat, and air. | yellow powder, hygroscopic; having an odor suggestive of cereals |
| Solubility | Freely soluble in dimethylformamide and in dimethylsulfoxide; slightly to sparingly soluble in methanol, in *n*-propyl alcohol, and in *n*-butyl alcohol; practically insoluble in water and in alcohol; insoluble in chloroform and in ether | corresponds |
| Identification<br><br>Identification A:<br>$A_{230} / A_{280}$<br>$A_{291} / A_{305}$<br>$A_{319} / A_{305}$<br>Identification, *Ultraviolet Absorption:* $A_{230} / A_{279\,(sh)}$ | Absorption maxima at 230 nm, 291 nm, 305 nm and 319 nm, and a shoulder at 280 nm.<br><br>0.83 to 1.25<br>0.61 to 0.73<br>0.83 to 0.96<br>0.90 to 1.25 | corresponds<br><br>1.05<br>0.64<br>0.90<br>1.07 |
| Identification: B, C, D, E | In conformity with BP 2011 and Eur. Ph. 8th Edition | corresponds |
| Absorbance at 305 nm | Not less than 0.60 | 0.8062 |
| Loss on drying: - USP 36<br>- BP 2011, Eur. Ph. 8th Edition | <br>Not more than 5.0 % | 1.60<br>3.39 |
| Heavy metals | Not more than 20 ppm | < 20 |
| Sulphated ash | Not more than 3.5 % | 0.64 |
| Assay: - USP 36<br><br>- BP 2011 / Eur. Ph. 8th Edition | Not less than 4400 USP Nystatin Units/mg, or, where intended for use in the extemporaneous preparation of oral suspensions, not less than 5000 USP Nystatin Units/mg<br>Minimum 4400 IU/ mg (dried substance) and minimum 5000 IU/mg (dried substance) if intended for oral administration | 6112<br><br>6326 |
| Abnormal toxicity | In conformity with BP 2011 and Eur. Ph. 8th Edition (2.6.9.) | corresponds |
| Suspendibility | Not less than 90.0 % | 93.66 |
| Crystallinity | It reveals birefringence | corresponds |
| pH (3.0 % aqueous suspension) | Between 6.0 and 8.0 | 7.60 |
| Composition:<br>USP 36: - Nystatin A1<br>- Any other individual component<br>BP 2011/Eur. Ph. 8th Edition:<br>- Nystatin A1<br>- Any other compound | <br>Not less than 85.0 %<br>Not more than 4.0 %<br><br>Minimum 85.0 %<br>Maximum 4.0 % | <br>89.12<br>1.81<br><br>89.66<br>1.87 |
| Microbiological quality<br>- TAMC, CFU/g<br>- TYMC, CFU /g<br>Specified micro-organisms:<br>- *Bile-tolerant gram-negative bacteria/g*<br>- *Escherichia coli/g*<br>- *Salmonella/g*<br>- *Pseudomonas aeruginosa/g*<br>- *Staphylococcus aureus/g* | <br>Not more than $10^3$<br>Not more than $10^2$<br><br>Absent<br>Absent<br>Absent<br>Absent<br>Absent | <br>35<br>< 1<br><br>absent<br>absent<br>absent<br>absent<br>absent |
| Residual solvents: - Methanol<br>- Acetone | Not more than 0.3 %<br>Not more than 0.5 % | NA<br>NA |
| Particle size,<br>≤ 45µm | As per client requirements | 97.07 |

04.06.2015

STORAGE: Store in an airtight container, protected from light, at a temperature of 2°C to 8°C.
Complies with the specification of the BP 2011, Eur. Ph. 8th Edition and USP 36.

Quality Director
Eng. Lavinia Dimitriu
12.06.2015

Head of Quality Control Department
Physico-Chemical Analyses
Pharm. Irinel Miftode
12.06.2015

Head of Quality Control Department
Microbiological and Pharmacodynamical Analyses
Biol. Marcela Strungariu
12.06.2015

Antibiotice SA
RO 1973096
J 22-285-1991

1, Valea Lupului Street
Iaşi 707410, Romania - România
P +40 232 209 000
P +40 372 065 000
F +40 232 209 633
E office@antibiotice.ro
www.antibiotice.ro