FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:
15F 12-801
Director Técnico

Antibiotice
Science and soul

CERTIFICATE OF ANALYSIS No. 2583

Product	NYSTATIN	
Analysis Record: 08.04.2015	Batch No. 401 8141	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 04.2015 Exp. Date 04.2018

ANALYSES PERFORMED	CONDITIONS	RESULTS
Appearance	Yellow or slightly brownish powder, hygroscopic. 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	Absorption maxima at 230 nm, 291 nm, 305 nm and 319 nm, and a shoulder at 280 nm.	corresponds
Identification A: A_{230} / A_{280} A_{291} / A_{305} A_{319} / A_{305} Identification, *Ultraviolet Absorption:* $A_{230} / A_{279\,(sh)}$	 0.83 to 1.25 0.61 to 0.73 0.83 to 0.96 0.90 to 1.25	 1.07 0.65 0.90 1.12
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	0.8197
Loss on drying: - USP 36 - BP 2011, Eur. Ph. 8th Edition	 Not more than 5.0 %	1.79 3.53
Heavy metals	Not more than 20 ppm	< 20
Sulphated ash	Not more than 3.5 %	0.90
Assay: - USP 36	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	6100
- BP 2011 / Eur. Ph. 8th Edition	Minimum 4400 IU/ mg (dried substance) and minimum 5000 IU/mg (dried substance) if intended for oral administration	6323
Abnormal toxicity	In conformity with BP 2011 and Eur. Ph. 8th Edition (2.6.9.)	corresponds
Suspendibility	Not less than 90.0 %	95.80
Crystallinity	It reveals birefringence	corresponds
pH (3.0 % aqueous suspension)	Between 6.0 and 8.0	7.44
Composition: USP 36: - Nystatin A1 - Any other individual component BP 2011/Eur. Ph. 8th Edition: - Nystatin A1 - Any other compound	 Not less than 85.0 % Not more than 4.0 % Minimum 85.0 % Maximum 4.0 %	 89.55 1.50 89.90 1.53
Microbiological quality - TAMC, CFU/g - TYMC, CFU /g Specified micro-organisms: - *Bile-tolerant gram-negative bacteria*/g - *Escherichia coli*/g - *Salmonella*/g - *Pseudomonas aeruginosa*/g - *Staphylococcus aureus*/g	 Not more than 10^3 Not more than 10^2 Absent Absent Absent Absent Absent	 40 < 1 absent absent absent absent absent
Residual solvents: - Methanol - Acetone	Not more than 0.3 % Not more than 0.5 %	0.05 0.27
Particle size, ≤ 45µm	As per client requirements	99.66

24.04.2015

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
24.04.2015

Head of Quality Control Department
Physico-Chemical Analyses
Sp. Pharm. Irinel Miftode
07.05.2015

Head of Quality Control Department
Microbiological and Pharmacodynamical Analyses
Biol. Marcela Strungariu
07.05.2015

Antibiotice 10 RO 1973006

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