Antibiotice
Science and soul

CERTIFICATE OF ANALYSIS No. 2250

Product	NYSTATIN	
Analysis Record: 07.03.2013	Batch No. 401 6253	Quantity: 87500 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. 035/2010/RO issued by NAMMD, valid starting with 04.06.2010. This batch has been manufactured, packaged and tested in accordance with EU GMP Guideline volume 4 part II (ICHQ7).		Mfg. Date 03.2013 Exp. Date 03.2016

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	 0.97 0.64 0.90 1.00
Identification: B, C, D, E	In conformity with BP 2011 and Eur. Ph. 7th Edition	corresponds
Absorbance at 305 nm	Not less than 0.60	0.7762
Loss on drying: - USP 35 - BP 2011, Eur. Ph. 7th Edition	 Not more than 5.0 %	1.50 3.25
Heavy metals	Not more than 20 ppm	< 20
Sulphated ash	Not more than 3.5 %	1.00
Assay: - USP 35	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. 7th Edition	Minimum 4400 IU/ mg (dried substance) and minimum 5000 IU/mg (dried substance) if intended for oral administration	6305
Abnormal toxicity	In conformity with BP 2011 and Eur. Ph. 7thEdition (2.6.9.)	corresponds
Suspendibility	Not less than 90.0 %	96.30
Crystallinity	It reveals birefringence	corresponds
pH (3.0 % aqueous suspension)	Between 6.0 and 8.0	7.58
Composition: USP 35: - Nystatin A1 - Any other individual component BP 2011/Eur. Ph. 7th Edition: - Nystatin A1 - Any other compound	 Not less than 85.0 % Not more than 4.0 % Minimum 85.0 % Maximum 4.0 %	 88.81 1.86 88.96 1.87
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	 30 < 1 absent absent absent absent absent
Residual solvents: - Methanol - Acetone	Not more than 0.3 % Not more than 0.5 %	0.01 0.22
Particle size, ≤ 45μm	Not less than 99.0 %	99.79

18.03.2013

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. 7th Edition and USP 35.

Quality Director
Eng. Lavinia Dimitriu
26.03.2013

Antibiotice S.A. Iaşi - România

Head of Quality Control Department
Physico-Chemical Analyses
Sp. Pharm. Irinel Miftode
26.03.2013

Head of Quality Control Department
Microbiological and Pharmacodynamical Analyses
Biol. Marcela Strungariu
26.03.2013

1, Valea Lupului, Street
Iaşi 707410, România
RO 1973096
J22/215/1991
P +40 232 209 000
P +40 372 065 000
F +40 232 209 633
E office@antibiotice.ro
www.antibiotice.ro