

CERTIFICATE OF ANALYSIS No. 8275

Product		NYSTATIN	
Analysis Record: 10.11.2014		Batch No. 401 7678	Quantity: 83000
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 11.2014 Exp. Date 11.2017
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 <i>n</i> -propyl alcohol, and in <i>n</i> -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:	0.83 to 1.25		1.03
A ₂₃₀ / A ₂₈₀	0.61 to 0.73		0.65
A ₂₉₁ / A ₃₀₅	0.83 to 0.96		0.90
A ₃₁₉ / A ₃₀₅	0.90 to 1.25		1.05
Identification, Ultraviolet Absorption: A ₂₃₀ / A ₂₇₉ (sh)	In conformity with BP 2011 and Eur. Ph. 7 th Edition		corresponds
Identification: B, C, D, E	Not less than 0.60		0.7874
Absorbance at 305 nm	Not more than 5.0 %		1.79
Loss on drying: - USP 36	Not more than 20 ppm		3.63
- BP 2011, Eur. Ph. 7 th Edition	Not more than 3.5 %		< 20
Heavy metals	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		1.08
Sulphated ash	Minimum 4400 IU/ mg (dried substance) and minimum 5000 IU/mg (dried substance) if intended for oral administration		6118
Assay: - USP 36	In conformity with BP 2011 and Eur. Ph. 7 th Edition (2.6.9.)		6348
- BP 2011 / Eur. Ph. 7 th Edition	Not less than 90.0 %		corresponds
Abnormal toxicity	It reveals birefringence		95.56
Suspendibility	Between 6.0 and 8.0		corresponds
Crystallinity	Not less than 85.0 %		7.27
pH (3.0 % aqueous suspension)	Not more than 4.0 %		88.99
Composition:	Minimum 85.0 %		2.20
USP 36: - Nystatin A1	Maximum 4.0 %		89.29
- Any other individual component	Not more than 10 ³		2.17
BP 2011/Eur. Ph. 7 th Edition:	Not more than 10 ²		40
- Nystatin A1	Absent		< 1
- Any other compound	Absent		absent
Microbiological quality	Absent		absent
- TAMC, CFU/g	Absent		absent
- TYMC, CFU /g	Absent		absent
Specified micro-organisms:	Absent		absent
- Bile-tolerant gram-negative bacterial/g	Absent		absent
- Escherichia coli/g	Absent		absent
- Salmonella/g	Absent		absent
- Pseudomonas aeruginosa/g	Absent		absent
- Staphylococcus aureus/g	Not more than 0.3 %		NA
Residual solvents: - Methanol	Not more than 0.5 %		NA
- Acetone	Not less than 97.0 %		97.67
Particle size, ≤ 45µm			

19.11.2014

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 36.

Quality Director Head of Quality Control Department

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Corresponde al lote de Fagron:

Director Técnico