

Antibiotice
Science and soul

FAGRON IBÉRICA, S.A.U
Corresponde al lote de fragon:

16E30-002

at

CERTIFICATE OF ANALYSIS No. 1098

Director Técnico

NYSTATIN

Product		
Analysis Record: 12.02.2016	Batch No. 401 8924	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: 02.2016 Exp. Date: 02.2019
ANALYSES PERFORMED		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	0.83 to 1.25	1.05
A 291 / A 305	0.61 to 0.73	0.64
A 319 / A 305	0.83 to 0.96	0.91
Identification, Ultraviolet Absorption: A 230 / A 279 (m)	0.90 to 1.25	1.08
Identification: B, C, D, E	In conformity with BP 2015 and Eur. Ph. 8 th Edition	corresponds
Absorbance at 305 nm	Not less than 0.60	0.8548
Loss on drying: - USP 38		1.90
- BP 2015, Eur. Ph. 8 th Edition	Not more than 5.0 %	3.73
Heavy metals	Not more than 20 ppm	< 20
Sulphated ash	Not more than 3.5 %	0.80
Assay: - USP 38	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	6150
- BP 2015 / Eur. Ph. 8 th Edition	Minimum 4400 IU/ mg (dried substance) and minimum 5000 IU/mg (dried substance) if intended for oral administration	6388
Abnormal toxicity	In conformity with BP 2015 and Eur. Ph. 8 th Edition (2.6.9.)	corresponds
Suspendibility	Not less than 90.0 %	94.51
Crystallinity	It reveals birefringence	corresponds
pH (3.0 % aqueous suspension)	Between 6.0 and 8.0	7.55
Composition:		
USP 38: - Nystatin A1	Minimum 85.0 %	89.80
- Any other individual component	Maximum 4.0 %	1.40
BP 2015/Eur. Ph. 8 th Edition:		
- Nystatin A1	Minimum 85.0 %	90.37
- Any other compound	Maximum 4.0 %	1.43
Microbiological quality		
- TAMC, CFU/g	Not more than 10 ³	30
- TYMC, CFU /g	Not more than 10 ²	< 1
Specified micro-organisms:		
- Bile-tolerant gram-negative bacteria/g	Absent	absent
- Escherichia coli/g	Absent	absent
- Salmonella/g	Absent	absent
- Pseudomonas aeruginosa/g	Absent	absent
- Staphylococcus aureus/g	Absent	absent
* Residual solvents: - Methanol	Not more than 0.3 %	NA
- Acetone	Not more than 0.5 %	NA
Particle size, ≤ 45µm, %	As per client requirements	97.73

*This analysis is carried out periodically (1 batch for every 4 batches manufactured).

04.03.2016

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 2015, Eur. Ph. 8th Edition and USP 38.

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