METAPHARMACEUTICAL

N DE LOTE:
0281025

24/10/2025

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Antibiotice
Science and soul

CERTIFICATE OF ANALYSIS No. 110514

Product	NYSTATIN Non-micronized Active Substance	
Analysis Record: 04.02.2025	Batch No. 401 3186	Quantity: 160.280 kg
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. 037/2022/RO issued by NAMMD, valid starting with 06.12.2022. This batch has been manufactured, packaged and tested in accordance with EU GMP Guideline volume 4 part II (ICHQ7).		Mfg. Date 02.2025 Re-test Date 02.2028

ANALYSES PERFORMED	ACCEPTANCE CRITERIA*	RESULTS
Appearance	A yellow or slightly brownish powder, hygroscopic.	corresponds
Solubility	Practically insoluble in water, freely soluble in dimethylformamide and in dimethyl sulphoxide, slightly soluble in methanol, practically insoluble in alcohol.	corresponds
Identification First indentification: B,E Second identification: A,C,D Identification A (UV): $A_{291} / A_{305\ nm}$ $A_{319} / A_{305\ nm}$ $A_{230} / A_{280\ nm}$	 0.61 to 0.73 0.83 to 0.96 0.83 to 1.25	 0.65 0.91 1.04
Identification B. IR	The spectrum obtained with the test solution must be similar with the IR spectrum obtained with Nystatin CRS	corresponds
Identification C. Colour reaction	A brown colour develops	corresponds
Identification D. Colour reaction	A brown colour develops that becomes violet on standing	corresponds
Identification E. HPLC	The principal peak in the chromatogram obtained with the test solution is similar in retention time to the principal peak in the chromatogram obtained with reference solution (a).	corresponds
Absorbance (at 305 nm)	Not less than 0.60	0.8350
Composition: - Nystatin A1 - Any other compound	 Minimum 85.0 % Maximum 4.0 %	 91.46 1.53
pH of the aqueous suspension 3%	Between 6.00 and 8.00	7.34
Loss on drying	Maximum 5.00 %	3.48
Sulphated ash	Maximum 3.50 %	0.94
Assay Potency of Nystatin	Minimum 5000 IU/mg (dried substance)	6604
Residual solvents: - Methanol - Acetone	 NMT 0.3 % NMT 0.5 %	 0.01 0.23
Microbiological quality - TAMC, CFU/g - TYMC, CFU /g	 NMT 10^3 NMT 10^2	 45 < 1
Particle size - 90 % of particles	 NMT 45 µm	 31.99

26.02.2025

*Current edition of EP Pharmacopoeia
STORAGE: Store in the original package, protected from light. No special temperature storage conditions are required.
We recommend that the product to be stored below 25°C.
Complies with S-SA 275/1 rev.07, EP

Quality Control Manager
Simona Olexici
26.02.2025

Manager of Physico-Chemical Analyses Laboratory
Geanina Rad
26.02.2025

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ANALYSES PERFORMED	ACCEPTANCE CRITERIA*	RESULTS
Description	Yellow to light tan powder. Is hygroscopic, and is affected by long exposure to light, heat, and air.	corresponds
Solubility	Freely soluble in dimethylformamide and in dimethyl sulfoxide; very slightly soluble in methanol; practically insoluble or insoluble in water, in alcohol, in n-propyl alcohol, in n-butyl alcohol,in chloroform, and in ether.	corresponds
Identification A. Infrared spectroscopy B. HPLC	 A. The IR spectrum obtained with the test solution must be similar with the IR spectrum obtained with Nystatin USP. B. The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the test for Composition.	 corresponds corresponds
Assay (potency)	Not less than 4400 USP Nystatin Units/mg Not less than 5000 **USP Nystatin Units/mg	6375
Composition: - Nystatin A1 - Any other individual component	 Minimum 85.0 % Maximum 4.0 %	 90.57 1.54
Residual solvents: - Methanol - Acetone	 NMT 0.3 % NMT 0.5 %	 0.01 0.23
**Crystallinity	The particles show birefringence	corresponds
pH (of the aqueous suspension 3%)	Between 6.00 and 8.00	7.34
Particle size - 90 % of particles	Not more than 45 µm	31.99
Loss on drying	Not more than 5.00 %	0.54
**Suspendibility	Not less than 90.0 %	92.9
Microbiological quality - TAMC, CFU/g - TYMC, CFU /g	Not more than 10^3 Not more than 10^2	45 < 1

26.02.2025

*Current edition of USP Pharmacopoeia
**The parameter should meet the requirements only when the product is intended for use in the extemporaneous preparation of oral suspensions.

STORAGE: Store below 25°C, in the original packaging, protected from light.
Complies with the specification No. 275/2 Rev. 07, USP

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