

Status: Currently Official on 16-Feb-2025

Official Date: Official Prior to 2013

Document Type: USP Monographs

DocID: GUID-B7380219-823B-4252-BFC6-C4FB5CCFE996_2_en-US

DOI: https://doi.org/10.31003/USPNF_M58175_02_01

DOI Ref: 69vic

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Nystatin and Triamcinolone Acetonide Ointment

» Nystatin and Triamcinolone Acetonide Ointment contains not less than 90.0 percent and not more than 140.0 percent of the labeled amount of USP Nystatin Units and not less than 90.0 percent and not more than 110.0 percent of the labeled amount of triamcinolone acetonide ($C_{24}H_{31}FO_6$).

Packaging and storage—Preserve in tight containers.

USP REFERENCE STANDARDS (11)—

[USP Nystatin RS](#)

[USP Triamcinolone Acetonide RS](#)

Identification—Place 2 g of Ointment in a conical flask, add 5.0 mL of chloroform, and shake for 10 minutes. Add 15 mL of alcohol, and shake for an additional 10 minutes. Filter the solution into a centrifuge tube, and evaporate the filtrate to dryness. Dissolve the residue in alcohol to obtain a solution containing about 250 μ g of triamcinolone acetonide per mL. Proceed as directed in the *Identification* test under [Triamcinolone Acetonide Cream](#), beginning with “Apply 10 μ L of this solution”: the specified result is observed.

MINIMUM FILL (755): meets the requirements.

WATER DETERMINATION, Method I (921): not more than 0.5%, 20 mL of a mixture of toluene and methanol (7:3) being used in place of methanol in the titration vessel.

Assay for nystatin—Proceed as directed for nystatin under [Antibiotics—Microbial Assays \(81\)](#), blending a suitable, accurately weighed portion of Ointment in a high-speed blender for 3 to 5 minutes with a sufficient, accurately measured volume of dimethylformamide to give a convenient concentration. Dilute an accurately measured volume of the solution so obtained quantitatively with dimethylformamide to obtain a stock solution containing about 400 USP Nystatin Units per mL. Dilute an accurately measured volume of this stock solution quantitatively with *Buffer B.6* to obtain a *Test Dilution* having a concentration of nystatin assumed to be equal to the median dose level of the Standard.

Assay for triamcinolone acetonide—Proceed with Ointment as directed in the [Assay](#) under [Triamcinolone Acetonide Cream](#), except to read “Ointment” in place of “Cream” throughout.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
NYSTATIN AND TRIAMCINOLONE ACETONIDE OINTMENT	Ying Han Associate Science & Standards Liaison	BIO42020 Biologics Monographs 4 - Antibiotics
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	BIO42020 Biologics Monographs 4 - Antibiotics

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. PF 28(1)

Current DocID: GUID-B7380219-823B-4252-BFC6-C4FB5CCFE996_2_en-US

Previous DocID: GUID-B7380219-823B-4252-BFC6-C4FB5CCFE996_1_en-US

DOI: https://doi.org/10.31003/USPNF_M58175_02_01

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