Status: Currently Official on 16-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-A7841FA8-A4C7-4F14-A2ED-08A2DF75734E_2_en-US
DOI: https://doi.org/10.31003/USPNF_M55840_02_01
DOI Ref: b98xb

Natamycin Ophthalmic Suspension

» Natamycin Ophthalmic Suspension is a sterile suspension of Natamycin in a suitable aqueous vehicle. It contains not less than 90.0 percent and not more than 125.0 percent of the labeled amount of $C_{33}H_{47}NO_{13}$. It contains one or more suitable preservatives.

Packaging and storage—Preserve in tight, light-resistant containers. The containers or individual cartons are sealed and tamper-proof so that sterility is assured at time of first use.

USP Reference standards ⟨11⟩—
USP Natamycin RS

Identification—Transfer a volume of Ophthalmic Suspension, equivalent to about 50 mg of natamycin, to a 200-mL volumetric flask, and add water to make a volume of 5 mL. Proceed as directed in the *Identification* test under *Natamycin*, beginning with "Add 100 mL of a 1 in 1000 solution of glacial acetic acid in methanol:" the specified result is obtained.

Sterility Tests ⟨71⟩ —It meets the requirements as directed for *Direct Inoculation of the Culture Medium* under *Test for Sterility of the Product to be Examined,* using 0.25 mL of the Ophthalmic Suspension taken from each container.

pH ⟨791⟩**:** between 5.0 and 7.5.

Assay—[Note—Throughout the *Assay* protect from direct light all solutions containing natamycin.]

Mobile phase, *Standard preparation, Resolution solution*, and *Chromatographic system*—Proceed as directed in the *Assay* under *Natamycin*.

Assay preparation—Transfer an accurately measured volume of Ophthalmic Suspension, equivalent to about 50 mg of natamycin, to a 250-mL volumetric flask. Add 12.5 mL of tetrahydrofuran, and sonicate for 10 minutes. Add 150 mL of methanol, and swirl to dissolve. Add 60 mL of water, and mix. Allow to cool to room temperature. Dilute with water to volume, and mix. Filter this solution through a suitable membrane filter of 0.5-µm or finer porosity.

Procedure—Proceed as directed in the *Assay* under *Natamycin*. Calculate the quantity, in mg, of $C_{33}H_{47}NO_{13}$ in each mL of the Ophthalmic Suspension taken by the formula:

$$0.25C(P_S/V)(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Natamycin RS in the *Standard preparation*, P_S is the stated content, in µg per mg, of USP Natamycin RS, V is the volume, in mL, of Ophthalmic Suspension taken, and r_U and r_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation,* respectively.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
NATAMYCIN OPHTHALMIC SUSPENSION	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: GUID-A7841FA8-A4C7-4F14-A2ED-08A2DF75734E_2_en-US
Previous DocID: GUID-A7841FA8-A4C7-4F14-A2ED-08A2DF75734E_1_en-US

DOI: https://doi.org/10.31003/USPNF_M55840_02_01
DOI ref: b98xb