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Miconazole Compounded Ophthalmic Solution

DEFINITION

Miconazole Compounded Ophthalmic Solution contains NLT 90.0% and NMT 110.0% of the labeled amount of miconazole ($C_{18}H_{14}Cl_4N_2O$).

Prepare Miconazole Compounded Ophthalmic Solution 1% (10 mg/mL) as follows (see *Pharmaceutical Compounding—Sterile Preparations ⟨797⟩*).

Miconazole	1 g
Polyoxyl 40 Hydrogenated Castor Oil	11.5 mL
Lactic Acid Solution (88%)	0.4 mL
Sterile Water for Injection, a sufficient amount to make	100 mL

Add the *Miconazole* to a sterile container and gradually add the *Polyoxyl 40 Hydrogenated Castor Oil*. Mix into a smooth viscous mixture. Add the *Lactic Acid Solution (88%)* and mix thoroughly. Add 80 mL of the *Sterile Water for Injection* and stir vigorously until the *Miconazole* is completely dissolved. Transfer the contents stepwise and quantitatively to a sterile calibrated container and bring to final volume with *Sterile Water for Injection*. Pass through a sterile filter of 0.22-µm pore size into an empty sterile dropper bottle. [Note—Room temperature *Sterile Water for Injection* should be used to assist in solubilization.]

ASSAY

• **Procedure**

Mobile phase: Dissolve 5.7 g of ammonium acetate in 380 mL of water, and add 320 mL of methanol and 300 mL of acetonitrile. Mix well.

Standard solution: 0.05 mg/mL of miconazole prepared from USP Miconazole RS in methanol

Sample solution: Transfer 0.5 mL of Ophthalmic Solution to a 100-mL volumetric flask, dilute with methanol to volume, and vortex to mix.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 230 nm

Column: 2.0-mm × 10-cm; 2.5-µm packing L1

Column temperature: 55°

Flow rate: 0.35 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for miconazole is about 18.0 min.]

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of miconazole ($C_{18}H_{14}Cl_4N_2O$) in the portion of Ophthalmic Solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of miconazole from the *Sample solution*

r_S = peak response of miconazole from the *Standard solution*

C_S = concentration of USP Miconazole RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of miconazole in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 2.9–3.9

• **Sterility Tests** ⟨71⟩, *Test for Sterility of the Product to Be Examined, Membrane Filtration***:** Meets the requirements

Change to read:

• ▲**Subvisible Particulate Matter in Intraocular Solutions** ⟨789⟩▲ (CN 1-May-2024) **:** Meets the requirements

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in sterile plastic ophthalmic dropper bottles for single-use in one patient only. Store in a refrigerator (2°–8°) or at controlled room temperature.

• **Beyond-Use Date:** In the absence of performing and completing a sterility test, the storage conditions in *Pharmaceutical Compounding – Sterile Preparations* ⟨797⟩, *14.3 Establishing a BUD for a CSP* apply. After successful completion of sterility testing, NMT 30 days after the date on which it was compounded when stored in a refrigerator (2°–8°); NMT 21 days after the date on which it was compounded when stored at controlled room temperature.

• **Labeling:** Label it to indicate that it is for ophthalmic use only and to state the *Beyond-Use Date*.

• **USP Reference Standards** ⟨11⟩

USP Miconazole RS

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

Topic/Question	Contact	Expert Committee
MICONAZOLE COMPOUNDED OPHTHALMIC SOLUTION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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