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Miconazole Nitrate Cream

DEFINITION

Miconazole Nitrate Cream contains NLT 90.0% and NMT 110.0% of the labeled amount of miconazole nitrate ($C_{18}H_{14}Cl_4N_2O \cdot HNO_3$).

IDENTIFICATION

- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

• PROCEDURE

Buffer: Triethylamine and water (10:1000). Adjust with phosphoric acid to a pH of 2.5.

Mobile phase: Methanol, acetonitrile, tetrahydrofuran, and *Buffer* (5:4:3:8)

Standard solution: 0.28 mg/mL of [USP Miconazole Nitrate RS](#) and 0.02 mg/mL of benzoic acid in *Mobile phase*

Sample solution: Nominally 0.28 mg/mL of miconazole nitrate in *Mobile phase* prepared as follows. Dissolve a weighed quantity of Cream in *Mobile phase*, and sonicate in a water bath at 40°–45° until the sample is completely dispersed. Cool the solution to below room temperature, and pass through a 0.45-μm Teflon filter into an HPLC vial.

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 225 nm

Column: 4.6-mm × 25-cm; packing L11

Column temperature: 45°

Flow rate: 1 mL/min

Injection volume: 10 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 13 between miconazole nitrate and benzoic acid

Column efficiency: NLT 7500 theoretical plates for the miconazole nitrate peak

Tailing factor: NMT 2.0 for the miconazole nitrate peak

Relative standard deviation: NMT 2.0% from the miconazole nitrate peak

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of miconazole nitrate ($C_{18}H_{14}Cl_4N_2O \cdot HNO_3$) in the portion of Cream taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

- [MINIMUM FILL \(755\)](#): Meets the requirements

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in collapsible tubes or tight containers, and store at controlled room temperature.
- **LABELING:** Cream that is packaged and labeled for use as a vaginal preparation shall be labeled Miconazole Nitrate Vaginal Cream.
- **USP REFERENCE STANDARDS (11):**
[USP Miconazole Nitrate RS](#)

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

Topic/Question	Contact	Expert Committee
MICONAZOLE NITRATE CREAM	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:

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