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Miconazole Nitrate Vaginal Suppositories

DEFINITION

Miconazole Nitrate Vaginal Suppositories contain 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.**

Sample: Place a portion of the *Sample stock solution* prepared as directed in the *Assay*, containing about 25 mg of miconazole nitrate, in a 50-mL beaker. Evaporate on a steam bath to dryness with the aid of a current of filtered air. Dry the residue at 105° for 10 min.

Acceptance criteria: The IR absorption spectrum of a potassium bromide dispersion of the residue obtained from the *Sample* exhibits maxima only at the same wavelengths as that of a similar preparation of USP Miconazole Nitrate RS.

ASSAY

• **Procedure**

Internal standard solution: 1 mg/mL of cholestane in a mixture of chloroform and methanol (1:1)

Standard solution: 2.5 mg/mL of USP Miconazole Nitrate RS prepared as follows. Transfer a 10.0-mL aliquot of a solution containing 500 µg/mL of USP Miconazole Nitrate RS in methanol to a test tube, and evaporate on a steam bath to dryness with the aid of a current of filtered air. Dissolve the residue in 2.0 mL of *Internal standard solution*.

Sample stock solution: Nominally 2.5 mg/mL of miconazole nitrate prepared as follows. Transfer 1 Suppository to a stoppered, 50-mL centrifuge tube. Add 30 mL of pentane, and shake by mechanical means for 20 min to dissolve the suppository base and to disperse the miconazole nitrate. Centrifuge to obtain a clear supernatant. Aspirate, and discard the clear liquid. Wash the residue with three 20-mL portions of pentane, shaking, centrifuging, and aspirating in the same manner. Discard the pentane washings. Evaporate the residual pentane from the residue with the aid of a current of filtered air. Using small portions of methanol, transfer the residue to a 100-mL volumetric flask. Dissolve in and dilute with methanol to volume.

Sample solution: Transfer an aliquot containing nominally the equivalent to 5 mg of miconazole nitrate from the *Sample stock solution* to a suitable container, and evaporate on a steam bath to dryness with the aid of a current of filtered air. Dissolve the residue in 2.0 mL of *Internal standard solution*.

Chromatographic system

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

Mode: GC

Detector: Flame ionization

Column: 2-mm × 1.2-m glass; packed with 3% phase G32 on support S1A

Temperatures

Column: 250°

Injection port: 250°

Detector: 300°

Carrier gas: Helium

Flow rate: 50 mL/min

Injection volume: 1 µL

System suitability

Sample: *Standard solution*

[Note—The relative retention times for cholestane and miconazole nitrate are 0.44 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.0 between the cholestane and miconazole nitrate peaks

Relative standard deviation: NMT 3.0% for replicate injections

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 Suppository taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = peak response ratio of miconazole nitrate to cholestane from the *Sample solution*

R_S = peak response ratio of miconazole nitrate to cholestane 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%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers at controlled room temperature.
- **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 VAGINAL SUPPOSITORIES	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

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