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## Butoconazole Nitrate Vaginal Cream

### DEFINITION

Butoconazole Nitrate Vaginal Cream contains Butoconazole Nitrate in a suitable cream base. It contains NLT 90.0% and NMT 110.0% of the labeled amount of butoconazole nitrate ( $C_{19}H_{17}Cl_3N_2S \cdot HNO_3$ ).

### IDENTIFICATION

#### • A.

**Sample solution:** Prepare a mixture of the *Standard solution* and the *Sample solution* (1:1), as directed in the Assay.

**Analysis:** Chromatograph the *Sample solution*, as directed in the Assay.

**Acceptance criteria:** The chromatogram exhibits two main peaks that correspond to butoconazole nitrate and the internal standard.

### ASSAY

#### • PROCEDURE

**Buffer:** 1.4 g of potassium acetate in 980 mL of water. Adjust with about 2 mL of glacial acetic acid to a pH of  $4.3 \pm 0.1$ , dilute with water to 1000 mL. Adjust the buffer molarity (0.018–0.072 M) as necessary to obtain suitable chromatographic performance. Increased retention time may be achieved by a decrease in the buffer molarity.

**Diluent:** Methanol and *Buffer* (60:40)

**Mobile phase:** Methanol and *Buffer* (65:35)

**Internal standard solution:** 1.6 mg/mL of 1-benzylimidazole in methanol

**Standard stock solution:** 0.4 mg/mL of [USP Butoconazole Nitrate RS](#) in methanol

**Standard solution:** Transfer 2.0 mL of the *Standard stock solution* and 3.0 mL of the *Internal standard solution* to a 50-mL flask, and add 35.0 mL of *Diluent*.

**Sample stock solution:** Nominally 0.4 mg/mL of butoconazole nitrate in methanol from Vaginal Cream prepared as follows. Add 200 mL of methanol to a 250-mL volumetric flask. Transfer to the flask a weighed quantity of Vaginal Cream equivalent to about 100 mg of butoconazole nitrate. Sonicate to dissolve, and cool to room temperature. Dilute with methanol to volume.

**Sample solution:** Transfer 2.0 mL of the *Sample stock solution* and 3.0 mL of the *Internal standard solution* to a 50-mL flask, and add 35.0 mL of *Diluent*. Allow the precipitated excipients that form to rise to the top of the solution, remove them by aspiration, and discard. Centrifuge or filter the remaining solution.

#### Chromatographic system

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

**Mode:** LC

**Detector:** UV 225 nm

**Column:** 4.6-mm  $\times$  25-cm; packing L9 that has been converted to the potassium form by the use of 0.555 M potassium acetate solution

**Flow rate:** 1 mL/min

**Injection volume:** 20  $\mu$ L

#### System suitability

**Sample:** *Standard solution*

[NOTE—The relative retention times for butoconazole nitrate and 1-benzylimidazole are 0.6 and 1.0, respectively.]

#### Suitability requirements

**Resolution:** NLT 4.0 between the analyte and internal standard peaks

**Column efficiency:** NLT 1100 theoretical plates for the analyte peak

**Tailing factor:** NMT 2.1 for the analyte peak

**Relative standard deviation:** NMT 1.5%

#### Analysis

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of butoconazole nitrate ( $C_{19}H_{17}Cl_3N_2S \cdot HNO_3$ ) in the portion of Vaginal Cream taken:

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

$R_U$  = peak response ratio of butoconazole nitrate to the internal standard from the *Sample solution*

$R_S$  = peak response ratio of butoconazole nitrate to the internal standard from the *Standard solution*

$C_s$  = concentration of [USP Butoconazole Nitrate RS](#) in the *Standard solution* (mg/mL)

$C_u$  = nominal concentration of butoconazole nitrate in the *Sample solution* (mg/mL)

**Acceptance criteria:** 90.0%–110.0% of the labeled amount

PERFORMANCE TESTS

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

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in collapsible tubes or tight containers. Avoid excessive heat, and avoid freezing.
- [USP REFERENCE STANDARDS \(11\)](#).  
[USP Butoconazole Nitrate RS](#)

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

Topic/Question	Contact	Expert Committee
BUTOCONAZOLE NITRATE VAGINAL CREAM	<a href="#">Documentary Standards Support</a>	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services <a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a>	SM12020 Small Molecules 1

**Chromatographic Database Information:** [Chromatographic Database](#)

Most Recently Appeared In:

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