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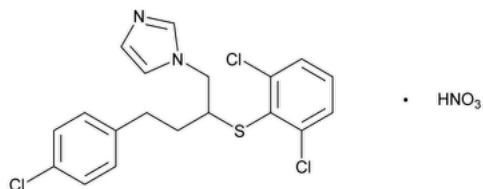
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Butoconazole Nitrate

 $C_{19}H_{17}Cl_3N_2S \cdot HNO_3$

474.79

1*H*-Imidazole, 1-[4-(4-chlorophenyl)-2-[(2,6-dichlorophenyl)thio]butyl]-, mononitrate, (±)-;(±)-1-[4-(*p*-Chlorophenyl)-2-[(2,6-dichlorophenyl) thio]butyl]imidazole mononitrate CAS RN[®]: 64872-77-1; UNII: 4805237NP5.

DEFINITION

Butoconazole Nitrate contains NLT 98.0% and NMT 102.0% of butoconazole nitrate ($C_{19}H_{17}Cl_3N_2S \cdot HNO_3$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#) ▲ (CN 1-MAY-2020)

ASSAY

PROCEDURE

Buffer: 2.18 g/L of monobasic potassium phosphate and 4.18 g/L of dibasic potassium phosphate in water**Mobile phase:** Methanol and *Buffer* (3:1)**Standard solution:** 0.2 mg/mL of [USP Butoconazole Nitrate RS](#) in *Mobile phase***Sample solution:** 0.2 mg/mL of Butoconazole Nitrate in *Mobile phase*. Filter.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)**Mode:** LC**Detector:** UV 229 nm**Column:** 4.6-mm × 25-cm; packing L1**Column temperature:** 40°**Flow rate:** 2 mL/min**Injection volume:** 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 2800 theoretical plates**Tailing factor:** NMT 1.5**Relative standard deviation:** NMT 1.5%

Analysis

Samples: *Standard solution* and *Sample solution*Calculate the percentage of butoconazole nitrate ($C_{19}H_{17}Cl_3N_2S \cdot HNO_3$) in the portion of Butoconazole Nitrate 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 Butoconazole Nitrate RS](#) in the *Standard solution* (mg/mL) C_U = concentration of Butoconazole Nitrate in the *Sample solution* (mg/mL)**Acceptance criteria:** 98.0%–102.0% on the dried basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%
- [ORDINARY IMPURITIES \(466\)](#)
Standard solutions: [USP Butoconazole Nitrate RS](#) in a mixture of methylene chloride and methanol (2:1)
Test solution: Butoconazole Nitrate in a mixture of methylene chloride and methanol (2:1)
Eluant: Chloroform, tetrahydrofuran, cyclohexane, and ammonium hydroxide (18:18:13:1)
Visualization: 22
Acceptance criteria: Meets the requirements

SPECIFIC TESTS

- [LOSS ON DRYING \(731\)](#)
Analysis: Dry under vacuum at 60° for 3 h.
Acceptance criteria: NMT 1.0%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed, light-resistant containers.
- [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	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: [Chromatographic Database](#)

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

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