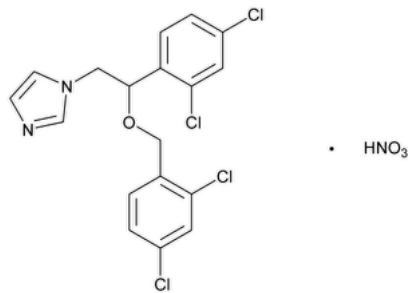


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Miconazole Nitrate

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$C_{18}H_{14}Cl_4N_2O \cdot HNO_3$ 479.14
1*H*-Imidazole, 1-[2-(2,4-dichlorophenyl)-2-[(2,4-dichlorophenyl)methoxy]ethyl]-, mononitrate;
1-[2,4-Dichloro-β-[(2,4-dichlorobenzyl)oxy]phenethyl]imidazole mononitrate CAS RN[®]: 22832-87-7; UNII: VW4H1CYW1K.

DEFINITION

Miconazole Nitrate contains NLT 98.0% and NMT 102.0% of miconazole nitrate ($C_{18}H_{14}Cl_4N_2O \cdot HNO_3$), calculated on the dried basis.

IDENTIFICATION

Change to read:

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

Solution A: [Methanol](#), [water](#), and [1 M triethylammonium acetate](#) (30:70:1)

Solution B: [Acetonitrile](#), [methanol](#), and [1 M triethylammonium acetate](#) (25:75:0.2)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	70	30
5	70	30
10	44	56
27	44	56
30	25	75
35	25	75
36	70	30
40	70	30

Diluent: [Methanol](#) and [water](#) (70:30)

System suitability solution: 0.1 mg/mL of [USP Miconazole Nitrate RS](#) and 6 µg/mL of [USP Miconazole Related Compound F RS](#) in *Diluent*.

Sonication may be needed to aid dissolution.

Standard solution: 0.1 mg/mL of [USP Miconazole Nitrate RS](#) in *Diluent*. Sonication may be needed to aid dissolution.

Sample solution: 0.1 mg/mL of Miconazole Nitrate in *Diluent*. Sonication may be needed to aid dissolution.

Chromatographic system

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

Mode: LC

Detector: UV 215 nm

Column: 4.6-mm × 10-cm; 2.6-µm packing [L11](#)

Column temperature: 40°

Flow rate: 0.8 mL/min

Injection volume: 10 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—The relative retention times for miconazole related compound F and miconazole are 0.96 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.5 between miconazole related compound F and miconazole, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 0.73%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of miconazole nitrate ($C_{18}H_{14}Cl_4N_2O \cdot HNO_3$) in the portion of Miconazole Nitrate 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 Nitrate RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Miconazole Nitrate in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.2%

• **ORGANIC IMPURITIES**

Solution A, Solution B, Mobile phase, Diluent, and Chromatographic system: Proceed as directed in the Assay.

Standard solution: 1.2 µg/mL each of [USP Miconazole Nitrate RS](#), [USP Econazole Nitrate RS](#), [USP Miconazole Related Compound C RS](#), [USP Miconazole Related Compound F RS](#), and [USP Miconazole Related Compound I RS](#) in *Diluent*

Sample solution: 600 µg/mL of Miconazole Nitrate in *Diluent*. Sonication may be needed to aid dissolution.

System suitability

Sample: *Standard solution*

[NOTE—See [Table 2](#) for relative retention times.]

Suitability requirements

Resolution: NLT 1.5 between miconazole related compound C and miconazole related compound I; NLT 1.5 between miconazole related compound I and econazole; and NLT 1.5 between miconazole related compound F and miconazole

Relative standard deviation: NMT 3.0% for miconazole

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of miconazole related compound C, miconazole related compound F, miconazole related compound I, or econazole nitrate in the portion of Miconazole Nitrate taken:

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

r_U = peak response of miconazole related compound C, miconazole related compound F, miconazole related compound I, or econazole nitrate from the *Sample solution*

r_S = peak response of miconazole related compound C, miconazole related compound F, miconazole related compound I, or econazole nitrate from the *Standard solution*

C_S = concentration of [USP Miconazole Related Compound C RS](#), [USP Miconazole Related Compound F RS](#), [USP Miconazole Related Compound I RS](#), or [USP Econazole Nitrate RS](#) in the *Standard solution* (µg/mL)