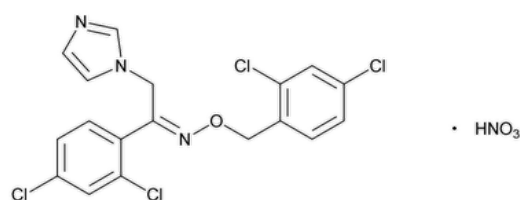


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Add the following:

^Oxiconazole Nitrate



$C_{18}H_{13}Cl_4N_3O \cdot HNO_3$ 492.14

Ethanone, 1-(2,4-dichlorophenyl)-2-(1H-imidazol-1-yl)-, O-[(2,4-dichlorophenyl)methyl]oxime, (Z)-, mononitrate;

2',4'-Dichloro-2-imidazol-1-ylacetophenone (Z)-[O-(2,4-dichlorobenzyl)oxime], mononitrate CAS RN®: 64211-46-7; UNII: RQ8UL4C17S.

DEFINITION

Oxiconazole Nitrate contains NLT 98.0% and NMT 102.0% of oxiconazole nitrate ($C_{18}H_{13}Cl_4N_3O \cdot HNO_3$), calculated on the dried basis.

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197K or 197A
- **B.** The retention time of the oxiconazole peak of the *Sample solution* corresponds to that of *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Solution A: 2.72 g/L of [monobasic potassium phosphate](#) in [water](#)

Mobile phase: [Acetonitrile](#) and *Solution A* (44:56). Adjust with phosphoric acid to a pH of 4.4.

Diluent: [Acetonitrile](#) and [water](#) (50:50)

Standard solution: 0.2 mg/mL of [USP Oxiconazole Nitrate RS](#) in *Diluent*. Sonicate, if necessary, to dissolve.

Sample solution: 0.2 mg/mL of Oxiconazole Nitrate in *Diluent*. Sonicate, if necessary, to dissolve.

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

Column: 4.6-mm × 15-cm; 3-μm packing [L1](#)

Column temperature: 40°

Flow rate: 1.2 mL/min

Injection volume: 10 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of oxiconazole nitrate ($C_{18}H_{13}Cl_4N_3O \cdot HNO_3$) in the portion of Oxiconazole Nitrate taken:

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

r_U = peak response of oxiconazole from the *Sample solution*

r_s = peak response of oxiconazole from the *Standard solution*

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

C_u = concentration of Oxiconazole 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**

[NOTE—Protect solutions containing oxiconazole from light and store in a refrigerator until ready to use.]

Buffer: 2.64 g/L of [dibasic ammonium phosphate](#) in water. Adjust with [phosphoric acid](#) to a pH of 7.0.

Solution A: [Acetonitrile](#) and *Buffer* (30:70)

Solution B: [Acetonitrile](#)

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

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
7	43	57
15	43	57
18	71	29
25	71	29
27	28	72
30	28	72
31	100	0
35	100	0

Standard stock solution 1: 1 mg/mL of [USP Oxiconazole Nitrate RS](#) in [acetonitrile](#)

Standard stock solution 2: 0.1 mg/mL each of [USP Oxiconazole Related Compound A RS](#), [USP Oxiconazole Related Compound B RS](#), [USP Oxiconazole Related Compound C RS](#), [USP Oxiconazole Related Compound D RS](#), and [USP Oxiconazole Related Compound E RS](#) in [acetonitrile](#)

Sensitivity solution: 0.5 µg/mL of [USP Oxiconazole Nitrate RS](#) from *Standard stock solution 1* in [acetonitrile](#)

Standard solution: 0.002 mg/mL of [USP Oxiconazole Nitrate RS](#) from *Standard stock solution 1* and 0.002 mg/mL each of [USP Oxiconazole Related Compound A RS](#), [USP Oxiconazole Related Compound B RS](#), [USP Oxiconazole Related Compound C RS](#), [USP Oxiconazole Related Compound D RS](#), and [USP Oxiconazole Related Compound E RS](#) from *Standard stock solution 2* in [acetonitrile](#)

Sample solution: 1 mg/mL of Oxiconazole Nitrate in [acetonitrile](#)

Chromatographic system

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

Mode: LC

Detector: UV 250 nm for oxiconazole related compound C and 225 nm for the remaining impurities

Column: 4.6-mm × 25-cm; 5-µm packing [L1](#)

Column temperature: 40°

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability