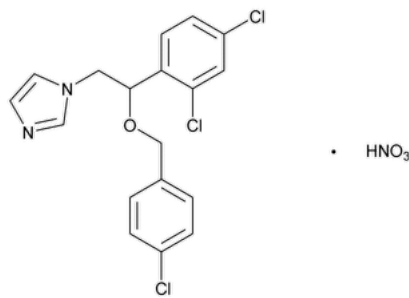


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Econazole Nitrate



$C_{18}H_{15}Cl_3N_2O \cdot HNO_3$ 444.70
1*H*-Imidazole, 1-[2-[(4-chlorophenyl)methoxy]-2-(2,4-dichlorophenyl)ethyl]-, mononitrate, (±)-;
(±)-1-[2,4-Dichloro-β-[(*p*-chlorobenzyl)oxy]phenethyl]-imidazole mononitrate CAS RN®: 24169-02-6; UNII: H438WYN10E.

DEFINITION
Econazole Nitrate contains NLT 98.0% and NMT 102.0% of econazole nitrate ($C_{18}H_{15}Cl_3N_2O \cdot HNO_3$), calculated on the dried basis.

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy: 197K**
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **C.**
Sample solution: 10 mg with 5 mL of water
Analysis: Shake the *Sample solution*, and cool the resulting suspension in ice. Keeping the suspension cool, add 0.4 mL of potassium chloride solution (1 in 10), 0.1 mL of diphenylamine TS, and, dropwise with shaking, 5 mL of sulfuric acid.
Acceptance criteria: An intense blue color develops.

ASSAY

- **PROCEDURE**
Solution A: 0.77 g/L of ammonium acetate in water
Solution B: Methanol and *Solution A* (20:80)
Solution C: Acetonitrile and methanol (60:40)
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution B (%)	Solution C (%)
0	60	40
25	10	90
27	10	90
27.1	60	40
30	60	40

Diluent: Methanol and water (40:60)
Standard solution: 0.4 mg/mL of [USP Econazole Nitrate RS](#) in *Diluent*. [NOTE—Sonication may be needed to dissolve the Standard.]
Sample solution: 0.4 mg/mL of Econazole Nitrate in *Diluent*. [NOTE—Sonication may be needed to dissolve the sample.]
Chromatographic system
(See [Chromatography \(621\), System Suitability](#).)

Mode: LC**Detector:** UV 225 nm**Column:** 4.6-mm × 10-cm; 3-μm packing L1**Column temperature:** 35°**Flow rate:** 1.5 mL/min**Injection volume:** 10 μL**System suitability****Sample:** *Standard solution***Suitability requirements****Tailing factor:** NMT 1.5**Relative standard deviation:** NMT 0.73%**Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of econazole nitrate ($C_{18}H_{15}Cl_3N_2O \cdot HNO_3$) in the portion of Econazole Nitrate taken:

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

 r_U = peak response of econazole from the *Sample solution* r_S = peak response of econazole from the *Standard solution* C_S = concentration of [USP Econazole Nitrate RS](#) in the *Standard solution* (mg/mL) C_U = concentration of Econazole 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%• **ORGANIC IMPURITIES****Mobile phase** and **Chromatographic system:** Proceed as directed in the Assay.**Standard solution:** 0.02 mg/mL each of [USP Econazole Related Compound A RS](#), [USP Econazole Related Compound B RS](#), and [USP Econazole Related Compound C RS](#), and 0.01 mg/mL of [USP Econazole Nitrate RS](#) in methanol**Sample solution:** 10 mg/mL of Econazole Nitrate in methanol**System suitability****Sample:** *Standard solution*[NOTE—See [Table 2](#) for the relative retention times.]**Suitability requirements****Resolution:** NLT 3.0 between econazole related compound C and econazole**Relative standard deviation:** NMT 3% for econazole related compound A, econazole related compound B, econazole related compound C, and econazole**Analysis****Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of econazole related compound A, econazole related compound B, or econazole related compound C in the portion of Econazole Nitrate taken:

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

 r_U = peak response of econazole related compound A, econazole related compound B, or econazole related compound C from the *Sample solution* r_S = peak response of econazole related compound A, econazole related compound B, or econazole related compound C from the *Standard solution* C_S = concentration of [USP Econazole Related Compound A RS](#), [USP Econazole Related Compound B RS](#), or [USP Econazole Related Compound C RS](#) in the *Standard solution* (mg/mL) C_U = concentration of Econazole Nitrate in the *Sample solution* (mg/mL)

Calculate the percentage of any other unspecified impurities in the portion of Econazole Nitrate taken:

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

 r_U = peak response of each impurity from the *Sample solution* r_S = peak response of econazole from the *Standard solution*