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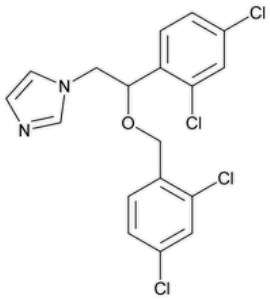
Miconazole



$C_{18}H_{14}Cl_4N_2O$ 416.13

1*H*-Imidazole, 1-2-[(2,4-dichlorophenyl)-2-[(2,4-dichlorophenyl)]methoxy]ethyl]-, (±)-;

(±)-1-[2,4-Dichloro-β-[(2,4-dichlorobenzyl)oxy] phenethyl]imidazole CAS RN®: 22916-47-8; UNII: 7NNO0D7S5M.

DEFINITION

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

IDENTIFICATION

Change to read:

- **A.** ▲Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: **197K**▲ (CN 1-May-2020)
- **B.**

Sample solution: Dissolve 40 mg in 50 mL of isopropyl alcohol in a 100-mL volumetric flask, and add 10 mL of 0.1 N hydrochloric acid. Dilute with isopropyl alcohol to volume.

Acceptance criteria: The UV absorption spectrum of the *Sample solution* exhibits maxima and minima at the same wavelengths as that of a similar solution of USP Miconazole RS, concomitantly measured.

ASSAY

- **Procedure**

Sample solution: 300 mg of Miconazole in 40 mL of glacial acetic acid. Add 4 drops of *p*-naphtholbenzein TS.

Titrimetric system

Mode: Direct titration

Titrant: 0.1 N perchloric acid VS

Endpoint detection: Visual

Analysis: Titrate the *Sample solution* with *Titrant* to a green endpoint. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N perchloric acid is equivalent to 41.61 mg of miconazole ($C_{18}H_{14}Cl_4N_2O$).

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

IMPURITIES

- **Residue on Ignition ⟨281⟩:** NMT 0.2%
- **Organic Impurities**

Standard solution A: 10 mg/mL of USP Miconazole RS in chloroform

Standard solution B: 100 µg/mL of USP Miconazole RS from *Standard solution A* in chloroform

Sample solution: 10 mg/mL in chloroform

Chromatographic system

(See *Chromatography ⟨621⟩, Thin-Layer Chromatography*.)

Mode: TLC

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture

Application volume: 5 µL

Developing solvent system: *n*-Hexane, chloroform, methanol, and ammonium hydroxide (60:30:10:1)

Analysis

Samples: *Standard solution A*, *Standard solution B*, and *Sample solution*

Apply the *Samples* separately to the starting line of the plate. Develop the chromatogram in a suitable chamber with freshly prepared *Developing solvent system* until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the chamber, and allow the solvent to evaporate. Expose the plate to iodine vapors in a closed chamber for 30 min, and locate the spots.

Acceptance criteria: The R_F value of the principal spot from the *Sample solution* corresponds to that from *Standard solution A*, and any other spot from the *Sample solution* does not exceed, in size or intensity, the principal spot from *Standard solution B* (1.0%).

SPECIFIC TESTS

- **Loss on Drying** ⟨731⟩

Analysis: Dry a sample under vacuum at 60° for 4 h.

Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers, protected from light. Store at 25°, excursions permitted between 15° and 30°.
- **USP Reference Standards** ⟨11⟩

USP Miconazole RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
MICONAZOLE	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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