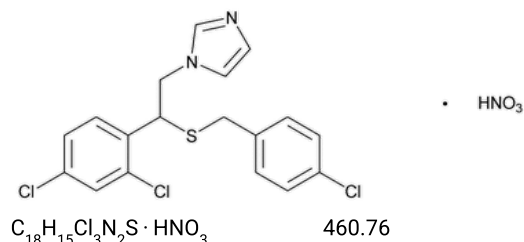


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Sulconazole Nitrate



1*H*-Imidazole, 1-[2-[[[(4-chlorophenyl)methyl]thio]-2-(2,4-dichlorophenyl)ethyl]-, mononitrate, (±)-;

(±)-1-[2,4-Dichloro-β-[(*p*-chlorobenzyl)thio] phenethyl]imidazole mononitrate CAS RN®: 61318-91-0; UNII: 1T89100D5U.

DEFINITION

Sulconazole Nitrate contains NLT 98.0% and NMT 102.0% of sulconazole nitrate ($C_{18}H_{15}Cl_3N_2S \cdot HNO_3$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K ▲](#) (CN 1-MAY-2020)
- **B.** [IDENTIFICATION TESTS—GENERAL \(191\), Nitrate](#): Meets the requirements of test A
- **C.** The retention time of the major peak for sulconazole of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Buffer: Dissolve 7.7 g of ammonium acetate in 992 mL of water and add 3.3 mL of glacial acetic acid. Pass through a suitable filter of 0.45-μm pore size under vacuum and degas with helium purging.

Solution A: Methanol, water, and *Buffer* (200:640:160)

Solution B: Methanol and acetonitrile (40:60)

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

Table 1

Time (min)	Solution A (%)	Solution B (%)
0.0	60	40
8.0	10	90
8.1	60	40
10.0	60	40

Diluent: Methanol and water (60:40)

Standard solution: 0.15 mg/mL of [USP Sulconazole Nitrate RS](#) in *Diluent*, prepared as follows. Transfer an appropriate quantity of [USP Sulconazole Nitrate RS](#) to a suitable volumetric flask, dissolve in 80% of the flask volume of *Diluent*, sonicate until dissolved, and dilute with *Diluent* to volume.

Sample solution: 0.15 mg/mL of Sulconazole Nitrate in *Diluent*, prepared as follows. Transfer an appropriate quantity of Sulconazole Nitrate to a suitable volumetric flask, dissolve in 80% of the flask volume of *Diluent*, sonicate until dissolved, and dilute with *Diluent* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 230 nm

Column: 2.1-mm × 10-cm; 1.7-μm packing L1

Flow rate: 0.5 mL/min

Injection volume: 5 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 sulconazole nitrate ($C_{18}H_{15}Cl_3N_2S \cdot HNO_3$) in the portion of Sulconazole 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 Sulconazole Nitrate RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Sulconazole 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**

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

Standard solution: 1.5 μg/mL each of [USP Sulconazole Nitrate RS](#) and [USP Sulconazole Related Compound A RS](#) in *Diluent*, prepared as follows. Transfer appropriate quantities of [USP Sulconazole Nitrate RS](#) and [USP Sulconazole Related Compound A RS](#) to a suitable volumetric flask, dissolve in 80% of the flask volume of *Diluent*, sonicate until dissolved, and dilute with *Diluent* to volume.

Sample solution: 1.5 mg/mL of Sulconazole Nitrate in *Diluent*, prepared as follows. Transfer an appropriate quantity of Sulconazole Nitrate to a suitable volumetric flask, dissolve in 80% of the flask volume of *Diluent*, sonicate until dissolved, and dilute with *Diluent* to volume.

System suitability

Sample: *Standard solution*

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

Suitability requirements

Relative standard deviation: NMT 2.0% for sulconazole nitrate and sulconazole related compound A

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of sulconazole related compound A in the portion of Sulconazole Nitrate taken:

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

r_U = peak response of sulconazole related compound A from the *Sample solution*

r_S = peak response of sulconazole related compound A from the *Standard solution*

C_S = concentration of [USP Sulconazole Related Compound A RS](#) in the *Standard solution* (mg/mL)

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

Calculate the percentage of any individual unspecified impurity in the portion of Sulconazole Nitrate taken:



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