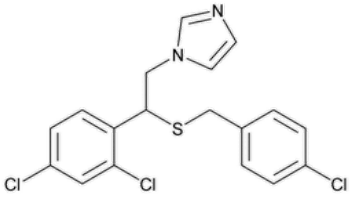
Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-119D2CE5-8D7A-459C-A175-A3BABB8C1584_4_en-US
DOI: https://doi.org/10.31003/USPNF_M78715_04_01
DOI Ref: qc7ba

Sulconazole Nitrate



• HNO_3

$C_{18}H_{15}Cl_3N_2S \cdot HNO_3$ 460.76

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:

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

r_U = peak response of any unspecified impurity from the *Sample solution*

r_S = peak response of sulconazole nitrate 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: See *Table 2*.

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Sulconazole related compound A	0.61	0.1
Sulconazole nitrate	1.0	—
Any individual unspecified impurity	—	0.10
Total impurities	—	2.0

SPECIFIC TESTS

- **Loss on Drying** ⟨731⟩

  Analysis: Dry under vacuum at 80° for 3 h.

  Acceptance criteria: NMT 1.0%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers, protected from light.
- **USP Reference Standards** ⟨11⟩

  USP Sulconazole Nitrate RS

  USP Sulconazole Related Compound A RS

  1-[2-(4-Chlorobenzyl)sulfinyl-2-(2,4-dichlorophenyl)ethyl]-1*H*-imidazole.

  $C_{18}H_{15}Cl_3N_2OS$ 413.74

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

Topic/Question	Contact	Expert Committee
SULCONAZOLE NITRATE	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 41(5)

Current DocID: GUID-119D2CE5-8D7A-459C-A175-A3BABB8C1584_4_en-US

DOI: https://doi.org/10.31003/USPNF_M78715_04_01

DOI ref: qc7ba