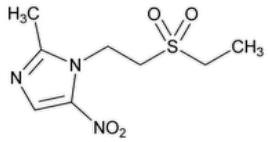
Status: Currently Official on 17-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-BEC00581-7442-4B26-A5CC-ADA2CC83DDDF_4_en-US
DOI: https://doi.org/10.31003/USPNF_M83700_04_01
DOI Ref: 0mb27

Tinidazole



$C_8H_{13}N_3O_4S$ 247.27

1*H*-Imidazole, 1-[2-(ethylsulfonyl)ethyl]-2-methyl-5-nitro-;

1-[2-(Ethylsulfonyl)ethyl]-2-methyl-5-nitroimidazole CAS RN®: 19387-91-8; UNII: 033KF7V46H.

DEFINITION

Tinidazole contains NLT 98.0% and NMT 102.0% of tinidazole ($C_8H_{13}N_3O_4S$), calculated on the dried basis.

IDENTIFICATION

Change to read:

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

• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Mobile phase: Acetonitrile, methanol, and water (10:20:70)

Standard solution: 0.1 mg/mL of USP Tinidazole RS prepared as follows. Transfer a suitable amount of USP Tinidazole RS to a suitable volumetric flask and add methanol to 10% of the final volume of the flask. Dilute with *Mobile phase* to volume.

Sample solution: 0.1 mg/mL of Tinidazole prepared as follows. Transfer a suitable amount of Tinidazole to a suitable volumetric flask and add methanol to 10% of the final volume of the flask. Dilute with *Mobile phase* to volume.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 320 nm

Column: 3.0-mm × 25-cm; 5-µm packing L7

Flow rate: 0.5 mL/min

Injection volume: 20 µL

Run time: 1.5 times the retention time of tinidazole

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 tinidazole ($C_8H_{13}N_3O_4S$) in the portion of Tinidazole taken:

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

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

r_S = peak response of tinidazole from the *Standard solution*

C_S = concentration of USP Tinidazole RS in the *Standard solution* (mg/mL)

C_U = concentration of Tinidazole 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, Sample solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

Standard stock solution 1: Use the *Standard solution* from the *Assay*.

Standard stock solution 2: 0.05 mg/mL each of USP Tinidazole Related Compound A RS and USP Tinidazole Related Compound B RS prepared as follows. Transfer suitable amounts of USP Tinidazole Related Compound A RS and USP Tinidazole Related Compound B RS to a suitable volumetric flask and add methanol to 10% of the final volume of the flask. Dilute with *Mobile phase* to volume.

Standard solution: 0.1 µg/mL of USP Tinidazole RS and 0.2 µg/mL each of USP Tinidazole Related Compound A RS and USP Tinidazole Related Compound B RS in *Mobile phase* from *Standard stock solution 1* and *Standard stock solution 2*

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 2.0 between tinidazole related compound A and tinidazole related compound B

Relative standard deviation: NMT 5.0% for each peak

Analysis

Samples: *Sample solution* and *Standard solution*

Calculate the percentages of tinidazole related compound A and tinidazole related compound B in the portion of Tinidazole taken:

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

r_U = peak response of tinidazole related compound A or tinidazole related compound B from the *Sample solution*

r_S = peak response of tinidazole related compound A or tinidazole related compound B from the *Standard solution*

C_S = concentration of USP Tinidazole Related Compound A RS or USP Tinidazole Related Compound B RS in the *Standard solution* (mg/mL)

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

Calculate the percentage of any unspecified impurity in the portion of Tinidazole taken:

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

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

r_S = peak response of tinidazole from the *Standard solution*

C_S = concentration of USP Tinidazole RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: See *Table 1*. Disregard any peak less than 0.05%.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Tinidazole related compound A	0.6	0.2
Tinidazole related compound B	0.7	0.2
Tinidazole	1.0	—

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Any unspecified impurity	—	0.10
Total impurities	—	0.4

SPECIFIC TESTS

• **Loss on Drying** ⟨731⟩

Analysis: Dry at 100°–105° to constant weight.

Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers, protected from light, at controlled room temperature.

• **USP Reference Standards** ⟨11⟩

USP Tinidazole RS

USP Tinidazole Related Compound A RS

2-Methyl-5-nitroimidazole.

$C_4H_5N_3O_2$ 127.10

USP Tinidazole Related Compound B RS

1-(2-Ethyl-sulfonylethyl)-2-methyl-4-nitroimidazole.

$C_8H_{13}N_3O_4S$ 247.28

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

Topic/Question	Contact	Expert Committee
TINIDAZOLE	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(4)

Current DocID: GUID-BEC00581-7442-4B26-A5CC-ADA2CC83DDDF_4_en-US

DOI: https://doi.org/10.31003/USPNF_M83700_04_01

DOI ref: 0mb27