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Add the following:

▲Tinidazole Tablets

DEFINITION
Tinidazole Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of tinidazole ($C_8H_{13}N_3O_4S$).

IDENTIFICATION
- **A.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.
- **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**

Buffer: 1.36 g/L of monobasic potassium phosphate in water

Mobile phase: Methanol and *Buffer* (20:80)

Standard solution: 0.1 mg/mL of USP Tinidazole RS in *Mobile phase*

Sample stock solution: Nominally 5 mg/mL of tinidazole from Tablets prepared as follows. Transfer an equivalent of about 500 mg of tinidazole from finely powdered Tablets (NLT 20), to a 100-mL volumetric flask. Add 75 mL of *Mobile phase*, mix thoroughly, and sonicate for 5 min. Cool to room temperature and dilute with *Mobile phase* to volume. Pass through a filter of 0.45-µm pore size and discard the first 8–10 mL of the filtrate.

Sample solution: Nominally 0.1 mg/mL of tinidazole in *Mobile phase* from *Sample stock solution*

Chromatographic system

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

Mode: LC

Detector: UV 315 nm. For *Identification A*, use a diode array detector in the range of 200–400 nm.

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection volume: 20 µL

Run time: NLT 2.6 times the retention time of tinidazole

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: 0.8–2.0

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of tinidazole ($C_8H_{13}N_3O_4S$) in the portion of Tablets 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 = nominal concentration of tinidazole in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: Water; 900 mL

Apparatus 1: 100 rpm

Time: 30 min

Standard solution: 0.0555 mg/mL of USP Tinidazole RS in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size, and dilute with *Medium* to obtain a concentration similar to that of the *Standard solution*.

Instrumental conditions

Mode: UV

Analytical wavelength: 277 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of tinidazole ($C_8H_{13}N_3O_4S$) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times V \times D \times (1/L) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

V = volume of *Medium*, 900 mL

D = dilution factor for the *Sample solution*

L = label claim (mg/Tablet)

Tolerances: NLT 80% (Q) of the labeled amount of tinidazole ($C_8H_{13}N_3O_4S$) is dissolved.

• **Uniformity of Dosage Units ⟨905⟩, *Weight Variation*:** Meet the requirements

IMPURITIES

• **Organic Impurities**

Buffer, Mobile phase, Sample stock solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

Sensitivity solution: 0.0005 mg/mL of USP Tinidazole RS in *Mobile phase*

System suitability solution: 0.01 mg/mL each of USP Tinidazole Related Compound A RS and USP Tinidazole Related Compound B RS in *Mobile phase*

Standard solution: 0.001 mg/mL of USP Tinidazole RS and 0.002 mg/mL each of USP Tinidazole Related Compound A RS and USP Tinidazole Related Compound B RS in *Mobile phase*

Sample solution: Nominally 1 mg/mL of tinidazole from *Sample stock solution* in *Mobile phase*

System suitability

Samples: *Sensitivity solution*, *System suitability solution*, and *Standard solution*

Suitability requirements

Resolution: NLT 1.5 between tinidazole related compound A and tinidazole related compound B, *System suitability solution*

Relative standard deviation: NMT 5.0% each for tinidazole, tinidazole related compound A, and tinidazole related compound B, *Standard solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of tinidazole related compound A and tinidazole related compound B in the portion of Tablets 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 = nominal concentration of tinidazole in the *Sample solution* (mg/mL)

Calculate the percentage of any unspecified impurity in the portion of Tablets 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 tinidazole from the *Standard solution*

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

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

Acceptance criteria: See *Table 1*. The reporting threshold is 0.05%.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Tinidazole related compound A	0.5	0.2
Tinidazole related compound B	0.6	0.2
Tinidazole	1.0	—
Any unspecified impurity	—	0.10
Total impurities	—	1.0

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers. Store 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-(Ethylsulfonyl)ethyl]-2-methyl-4-nitroimidazole.

$C_8H_{13}N_3O_4S$ 247.27▲ (USP 1-May-2023)

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

Topic/Question	Contact	Expert Committee
TINIDAZOLE TABLETS	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

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