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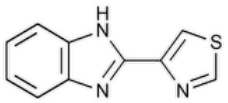
Thiabendazole



$C_{10}H_7N_3S$ 201.25

1*H*-Benzimidazole, 2-(4-thiazolyl)-;

2-(4-Thiazolyl)benzimidazole CAS RN®: 148-79-8; UNII: N1Q45E87DT.

Change to read:

DEFINITION

Thiabendazole contains NLT 98.0% and NMT 101.0% of thiabendazole ($C_{10}H_7N_3S$), calculated on the dried basis.

[NOTE—Thiabendazole labeled solely for veterinary use is exempt from the requirements of the tests for *Residue on Ignition ⟨281⟩*▲▲ (USP 1-Aug-2022) and *Organic Impurities*.]

IDENTIFICATION

Change to read:

• **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** 197K. Do not dry ▲the Standard nor the Sample.▲ (USP 1-Aug-2022)

Change to read:

• **B. Spectroscopic Identification Tests ⟨197⟩, *Ultraviolet-Visible Spectroscopy*:** 197U

▲**Standard solution:** 5 µg/mL of USP Thiabendazole RS in 0.1 N hydrochloric acid▲ (USP 1-Aug-2022)

Sample solution: 5 µg/mL in 0.1 N hydrochloric acid

Acceptance criteria: Meets the requirements

• **C.**

Solution A: Dissolve 20 g of ferric ammonium sulfate in 75 mL of water, add 10 mL of 1 N sulfuric acid, and dilute with water to 100 mL.

Sample: 5 mg of Thiabendazole

Analysis: Dissolve the *Sample* in 5 mL of 0.1 N hydrochloric acid, add 3 mg of *p*-phenylenediamine dihydrochloride, and shake to dissolve. Add 0.1 g of zinc dust, mix, and allow to stand for 2 min. Add 5 mL of *Solution A*.

Acceptance criteria: A blue or blue-violet color develops.

• **D.** The R_F value of the principal spot of the *Identification solution* corresponds to that of *Standard solution A*, as obtained in the test for *Organic Impurities*.

ASSAY

• **Procedure**

Sample: 160 mg of Thiabendazole

Analysis: Dissolve the *Sample* in 10 mL of glacial acetic acid. Add 50 mL of acetic anhydride, 1 mL of mercuric acetate TS, and 2 drops of crystal violet TS. Titrate with 0.1 N perchloric acid VS (the color change at the endpoint is from blue to blue-green). Perform a blank determination, and make any necessary correction. Each milliliter of 0.1 N perchloric acid is equivalent to 20.13 mg of thiabendazole ($C_{10}H_7N_3S$).

Acceptance criteria: 98.0%–101.0% on the dried basis

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.1%

Delete the following:

▲• **Selenium ⟨291⟩**

Sample: 200 mg of Thiabendazole

Acceptance criteria: NMT 0.003%▲ (USP 1-Aug-2022)

• **Organic Impurities**

Standard stock solution: 1.0 mg/mL of USP Thiabendazole RS in glacial acetic acid

Standard solutions: Dilute *Standard stock solution* as per *Table 1* with glacial acetic acid to obtain *Standard solutions A*, *B*, and *C* having the following compositions:

Table 1

Standard solution	Dilution	Concentration (µg/mL)	Percentage (%, for Comparison with Sample)
A	1 in 4	250	0.5
B	3 in 20	150	0.3
C	1 in 20	50	0.1

Sample solution: 50 mg/mL of Thiabendazole in glacial acetic acid

Identification solution: 0.25 mg/mL of Thiabendazole in glacial acetic acid, from *Sample solution*

Chromatographic system

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

Mode: TLC

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture

Application volume: 10 µL

Developing solvent system: Toluene, glacial acetic acid, acetone, and water (60:20:8:2)

Analysis

Samples: *Standard solutions*, *Sample solution*, and *Identification solution*

Develop in the *Developing solvent system* until the solvent front has moved three-fourths of the length of the plate. Remove the plate from the developing chamber, mark the solvent front, and allow the solvent to evaporate. Examine the plate under short-wavelength UV light, and compare the intensities of any secondary spots observed in the chromatogram of the *Sample solution* with those of the principal spots in the chromatograms of the *Standard solutions*.

Acceptance criteria: No secondary spot from the chromatogram of the *Sample solution* is larger or more intense than the principal spot of the *Standard solution* (NMT 0.5%), and the sum of the intensities of all secondary spots of the *Sample solution* corresponds to NMT 1.0%.

SPECIFIC TESTS

• **Melting Range or Temperature ⟨741⟩:** 296°–303°

• **Loss on Drying ⟨731⟩**

Sample: Dry in vacuum at 100° for 2 h.

Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers.

• **USP Reference Standards ⟨11⟩**

USP Thiabendazole RS

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

Topic/Question	Contact	Expert Committee
THIABENDAZOLE	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:
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