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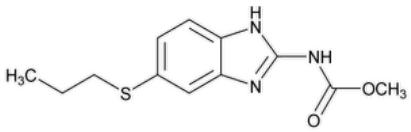
Albendazole



$C_{12}H_{15}N_3O_2S$ 265.33

Carbamic acid, [5-(propylthio)-1*H*-benzimidazol-2-yl]-, methyl ester;

Methyl 5-(propylthio)-2-benzimidazolecarbamate CAS RN®: 54965-21-8; UNII: F4216019LN.

DEFINITION

Albendazole contains NLT 98.0% and NMT 102.0% of albendazole ($C_{12}H_{15}N_3O_2S$), calculated on the dried basis.

IDENTIFICATION

Change to read:

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

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

ASSAY

• **Procedure**

Sample: 250 mg of Albendazole

Analysis: Transfer the *Sample* to a suitable flask, and dissolve in 100 mL of glacial acetic acid, warming gently if necessary. Cool, and titrate with 0.1 N perchloric acid VS to a potentiometric endpoint (see *Titrimetry* ⟨541⟩). Perform a blank determination. Each mL of 0.1 N perchloric acid is equivalent to 26.53 mg of $C_{12}H_{15}N_3O_2S$.

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

• **Residue on Ignition** ⟨281⟩**:** NMT 0.2%

• **Organic Impurities**

Standard stock solution: 5 mg/mL of USP Albendazole RS in glacial acetic acid

Standard solution: 0.05 mg/mL of USP Albendazole RS in glacial acetic acid from *Standard stock solution*

Sample solution: 10 mg/mL in glacial acetic acid

Chromatographic system

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

Mode: TLC

Adsorbant: 0.25-mm layer of silica gel mixture

Application volume: 10 µL

Developing solvent system: Chloroform, ether, and glacial acetic acid (60:10:10)

Analysis: Proceed as directed for *Chromatography* ⟨621⟩, *Thin-Layer Chromatography*.

Samples: *Standard stock solution*, *Standard solution*, and *Sample solution*

Develop the chromatogram in the *Developing solvent system* until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber, mark the solvent front, allow the solvent to evaporate from the plate, and examine the plate under short-wavelength UV light.

Acceptance criteria: 0.5%; no spot, other than the principal spot of the *Sample solution*, is larger or more intense than the principal spot of the *Standard solution*.

SPECIFIC TESTS

• **Loss on Drying** ⟨731⟩

Analysis: Dry at 105° for 4 h.

Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers, and store at controlled room temperature.
- **USP Reference Standards** ⟨11⟩
  USP Albendazole RS

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

Topic/Question	Contact	Expert Committee
ALBENDAZOLE	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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