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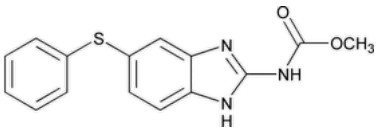
Fenbendazole



$C_{15}H_{13}N_3O_2S$ 299.35

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

Methyl 5-(phenylthio)-2-benzimidazolecarbamate CAS RN®: 43210-67-9; UNII: 621BVT9M36.

DEFINITION

Fenbendazole contains NLT 98.0% and NMT 101.0% of fenbendazole ($C_{15}H_{13}N_3O_2S$), calculated on the dried basis.

IDENTIFICATION

Change to read:

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

ASSAY

• **Procedure**

Sample: 200 mg

Analysis: Dissolve the *Sample* in 30 mL of glacial acetic acid, warming if necessary to effect solution. Allow to cool, and titrate with 0.1 N perchloric acid VS, determining the endpoint potentiometrically. Each mL of 0.1 N perchloric acid is equivalent to 29.94 mg of fenbendazole ($C_{15}H_{13}N_3O_2S$).

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

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.3%

• **Organic Impurities**

Solution A: Methanol, acetic acid, and water (30:1:70)

Solution B: Methanol, acetic acid, and water (70:1:30)

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
10	0	100
40	0	100
50	100	0

Diluent: Methanol and hydrochloric acid (99:1)

System suitability stock solution: 0.1 mg/mL each of USP Fenbendazole RS and USP Mebendazole RS in methanol

System suitability solution: 0.01 mg/mL each of USP Fenbendazole RS and USP Mebendazole RS from the *System suitability stock solution* in *Diluent*

Standard stock solution A: 0.025 mg/mL of USP Fenbendazole RS prepared as follows. Dissolve a weighed quantity of USP Fenbendazole RS in *Diluent* to obtain a solution with a known concentration of 5 mg/mL. Dilute 1.0 mL of this solution with methanol to 200.0 mL.

Standard solution A: 0.0125 mg/mL of USP Fenbendazole RS from *Standard stock solution A* in *Diluent*

Standard stock solution B: 0.1 mg/mL of USP Fenbendazole Related Compound A RS in methanol

Standard solution B: 0.01 mg/mL of USP Fenbendazole Related Compound A RS from *Standard stock solution B* in *Diluent*

Standard stock solution C: 0.1 mg/mL of USP Fenbendazole Related Compound B RS in methanol

Standard solution C: 0.01 mg/mL of USP Fenbendazole Related Compound B RS from *Standard stock solution C* in *Diluent*

Sample solution: Dissolve 5.0 mg/mL of Fenbendazole in *Diluent*.

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

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

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

Sample: *System suitability solution*

[Note—The relative retention times for mebendazole and fenbendazole are about 0.85 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.5 between mebendazole and fenbendazole

Analysis

Samples: *Standard solution A*, *Standard solution B*, *Standard solution C*, and *Sample solution*

Calculate the percentages of fenbendazole related compound A and fenbendazole related compound B in the portion of Fenbendazole taken:

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

r_U = peak response of each related compound from the *Sample solution*

r_S = peak response of the corresponding related compound from *Standard solution B* or *Standard solution C*

C_S = concentration of the corresponding related compound in *Standard solution B* or *Standard solution C* (mg/mL)

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

Calculate the percentage of any other impurity in the portion of Fenbendazole taken:

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

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

r_S = peak response of USP Fenbendazole RS from *Standard solution A*

C_S = concentration of USP Fenbendazole RS in *Standard solution A* (mg/mL)

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

Acceptance criteria: See *Table 2*. The reporting level for impurities is 0.1%.

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Fenbendazole related compound A	0.25	0.5
Fenbendazole related compound B	0.65	0.5
Fenbendazole	1.0	—
Any individual impurity	—	0.5
Total impurities	—	1

SPECIFIC TESTS

- **Loss on Drying ⟨731⟩**

Analysis: Dry at 100°–105° for 3 h.

Acceptance criteria: NMT 1.0%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed, light-resistant containers, and store at room temperature.
- **Labeling:** Label to indicate that it is for veterinary use only.
- **USP Reference Standards** ⟨11⟩

USP Fenbendazole RS

USP Fenbendazole Related Compound A RS

Methyl (1*H*-benzimidazole-2-yl)carbamate.

$C_9H_9N_3O_2$ 191.19

USP Fenbendazole Related Compound B RS

Methyl [5(6)-chlorobenzimidazole-2-yl]carbamate.

$C_9H_8ClN_3O_2$ 225.63

USP Mebendazole RS

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

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

Chromatographic Database Information: Chromatographic Database

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