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Mebendazole Tablets

DEFINITION

Mebendazole Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of mebendazole ($C_{16}H_{13}N_3O_3$).

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**

Solution A: 7.5 g/L of ammonium acetate in *water*

Solution B: *Acetonitrile*

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	80	20
15	70	30
20	10	90
25	10	90
26	80	20
30	80	20

Diluent: *N,N*-Dimethyl formamide

Standard solution: 0.05 mg/mL of USP Mebendazole RS in *Diluent*. Sonicate, if necessary, to dissolve.

Sample solution: Nominally 0.05 mg/mL of mebendazole in *Diluent*, prepared as follows. Transfer a suitable quantity of mebendazole from NLT 20 finely powdered Tablets into a suitable volumetric flask. Add *Diluent* to about 80% of the flask volume and sonicate for 30 min. Dilute with *Diluent* to volume and pass through a suitable filter of 0.45-µm pore size.

Chromatographic system

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

Mode: LC

Detector: UV 250 nm. For *Identification A*, use a diode array detector in the range of 200–400 nm.

Column: 4.6-mm × 10-cm; 3-µm packing L1

Column temperature: 40°

Flow rate: 1.2 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of mebendazole ($C_{16}H_{13}N_3O_3$) in the portion of Tablets taken:

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

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

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

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

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution** ⟨711⟩

Medium: 0.1 N hydrochloric acid containing 1.0% sodium lauryl sulfate; 900 mL

Apparatus 2: 75 rpm

Time: 120 min

Solution A: Dissolve 8.0 g of sodium hydroxide in 2 L of *water*. Add 3.0 g of sodium lauryl sulfate, and mix. Add 20 mL of *phosphoric acid*, and adjust with *phosphoric acid* to a pH of 2.5.

Mobile phase: *Acetonitrile* and *Solution A* (3:7)

Standard solution: 0.5 mg/mL of USP Mebendazole RS prepared as follows. Transfer the appropriate amount of USP Mebendazole RS to a volumetric flask. Add 20% of the final volume of formic acid, and dissolve. Dilute with *methanol* to volume. Dilute a portion of this solution with *Medium* to obtain a solution having a known concentration similar to the expected concentration in the solution under test.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 3-cm; packing L7

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis: Determine the percentage of mebendazole ($C_{16}H_{13}N_3O_3$) dissolved.

Tolerances: NLT 75% (*Q*) of the labeled amount of mebendazole ($C_{16}H_{13}N_3O_3$) is dissolved.

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

IMPURITIES

• **Organic Impurities**

Solution A, Solution B, Mobile phase, Diluent, and **Chromatographic system:** Proceed as directed in the *Assay*.

System suitability solution: 0.1 mg/mL of USP Mebendazole RS and 0.002 mg/mL of USP Mebendazole Related Compound D RS in *Diluent*. Sonicate, if necessary, to dissolve.

Standard solution: 0.002 mg/mL of USP Mebendazole RS in *Diluent*. Sonicate, if necessary, to dissolve.

Sample solution: Nominally 1 mg/mL of mebendazole in *Diluent*, prepared as follows. Transfer a suitable quantity of mebendazole from NLT 20 powdered Tablets into a suitable volumetric flask. Add *Diluent* to about 40% of the flask volume and sonicate for about 30 min. Dilute with *Diluent* to volume and pass through a suitable filter of 0.45-µm pore size.

System suitability

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

Suitability requirements

Resolution: NLT 1.5 between mebendazole and mebendazole related compound D, *System suitability solution*

Relative standard deviation: NMT 5.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each 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 each impurity from the *Sample solution*

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

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

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

Acceptance criteria: See *Table 2*. Disregard any peak below 0.05%.

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Mebendazole	1.0	—
Mebendazole related compound D[a]	1.1	—
Any individual unspecified impurity	—	0.2
Total impurities	—	1.0

[a] This is a process-related impurity and not included in the total impurities.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers.
- **USP Reference Standards** ⟨11⟩

USP Mebendazole RS

USP Mebendazole Related Compound D RS

Methyl 5-benzoyl-1-methylbenzimidazol-2-yl carbamate.

$C_{17}H_{15}N_3O_3$ 309.32

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

Topic/Question	Contact	Expert Committee
MEBENDAZOLE TABLETS	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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