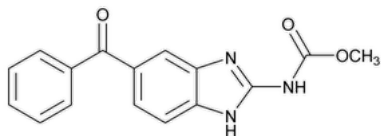


Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-E3D6D29A-00DC-45EB-8421-F36A11D17B1B_5_en-US
DOI: https://doi.org/10.31003/USPNF_M47510_05_01
DOI Ref: t274y

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Mebendazole



$C_{16}H_{13}N_3O_3$

295.29

Carbamic acid, (5-benzoyl-1H-benzimidazol-2-yl), methyl ester;

Methyl 5-benzoyl-2-benzimidazolecarbamate CAS RN®: 31431-39-7; UNII: 81G6I5V05I.

DEFINITION

Mebendazole contains NLT 98.0% and NMT 102.0% of mebendazole ($C_{16}H_{13}N_3O_3$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#) ▲ (CN 1-MAY-2020)
- **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

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: Acetonitrile and water (50:50)

System suitability solution: 50 µg/mL of [USP Mebendazole RS](#) and 2.5 µg/mL of [USP Mebendazole Related Compound D RS](#) in *Diluent*.

Sonicate in *Diluent* using 80% of the final volume at 45°–50° for 10 min. Dilute with *Diluent* to final volume.

Standard solution: 0.05 mg/mL of [USP Mebendazole RS](#) in *Diluent*. Sonicate in *Diluent* using 80% of the final volume at 45°–50° for 10 min.

Dilute with *Diluent* to final volume.

Sample solution: 0.05 mg/mL of Mebendazole in *Diluent*. Sonicate in *Diluent* using 80% of the final volume at 45°–50° for 10 min. Dilute with *Diluent* to final volume.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 250 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

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

[NOTE—The relative retention times of mebendazole and mebendazole related compound D are 1.0 and 1.2, respectively.]

Suitability requirements

Resolution: NLT 5.0 between mebendazole and mebendazole related compound D, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 0.73%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of mebendazole ($C_{16}H_{13}N_3O_3$) in the portion of Mebendazole 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 = concentration of Mebendazole in the *Sample solution* (mg/mL)

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

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

• **ORGANIC IMPURITIES**

Solution A, Solution B, Mobile phase, Diluent, System suitability solution, Sample solution, and Chromatographic system: Prepare as directed in the Assay.

Standard solution: 2.5 µg/mL of [USP Mebendazole RS](#) in *Diluent*

System suitability

Sample: *System suitability solution*

Suitability requirements

Resolution: NLT 5.0 between the mebendazole and mebendazole related compound D peaks

Relative standard deviation: NMT 1.0% for the mebendazole peak and NMT 5.0% for the mebendazole related compound D peak

Analysis

Samples: *Sample solution* and *Standard solution*

Calculate the percentage of each impurity in the portion of Mebendazole taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

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

F = relative response factor (see [Table 2](#))

Acceptance criteria: See [Table 2](#). Disregard peaks less than 0.05%.

Table 2

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
2-Amino mebendazole ^a	0.46	1.0	0.25
2-Hydroxy mebendazole ^b	0.53	1.0	0.25



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