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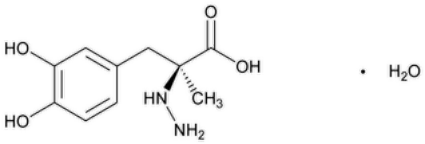
Carbidopa



$C_{10}H_{14}N_2O_4 \cdot H_2O$ 244.24
$C_{10}H_{14}N_2O_4$ 226.23

Benzenepropanoic acid, α-hydrazino-3,4-dihydroxy-α-methyl-, monohydrate, (*S*)-;
(−)-L-α-Hydrazino-3,4-dihydroxy-α-methylhydrocinnamic acid monohydrate CAS RN®: 38821-49-7; UNII: MNX7R8C5VO.
Anhydrous CAS RN®: 28860-95-9; UNII: KR87B45RGH.

DEFINITION

Carbidopa contains NLT 98.0% and NMT 102.0% of carbidopa ($C_{10}H_{14}N_2O_4 \cdot H_2O$).

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197M**▲ (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**

Buffer: 0.05 M monobasic sodium phosphate, adjusted with phosphoric acid to a pH of 2.7

Mobile phase: Alcohol and *Buffer* (5:95)

System suitability solution: 0.1 mg/mL of USP Carbidopa RS and 0.1 mg/mL of USP Methyldopa RS in *Mobile phase*

Standard solution: 0.5 mg/mL of USP Carbidopa RS in *Mobile phase*. [Note—Use gentle heat and ultrasonification, if necessary, to dissolve.]

Sample solution: 0.5 mg/mL of Carbidopa in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Column: 3.9-mm × 30-cm; packing L1

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

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

[Note—The relative retention times for methyldopa and carbidopa are about 0.8 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 0.9 between methyldopa and carbidopa, *System suitability solution*

Relative standard deviation: NMT 1.5%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the concentration, in mg/mL, of carbidopa ($C_{10}H_{14}N_2O_4 \cdot H_2O$) in the *Standard solution* (C_S):

$$\text{Result} = C_{S2} \times (M_{r1}/M_{r2})$$

C_{S2} = concentration of USP Carbidopa RS, as determined using the value on the USP Reference Standard label, in the *Standard solution* (mg/mL)

M_r = molecular weight of carbidopa monohydrate, 244.24

M_r = molecular weight of anhydrous carbidopa, 226.23

$_2$

Calculate the percentage of carbidopa ($C_{10}H_{14}N_2O_4 \cdot H_2O$) in the portion of Carbidopa taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of carbidopa ($C_{10}H_{14}N_2O_4 \cdot H_2O$) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 98.0%–102.0%

IMPURITIES

- **Residue on Ignition ⟨281⟩:** NMT 0.1%
- **Limit of Methyldopa and Carbidopa Related Compound A**

Mobile phase, System suitability solution, Standard solution, Sample solution, Chromatographic system, and **System suitability:** Proceed as directed in the *Assay*.

Impurity standard solution: 2.5 µg/mL of USP Methyldopa RS and 2.5 µg/mL of USP Carbidopa RS in *Mobile phase*

Analysis

Samples: *Sample solution* and *Impurity standard solution*

[Note—The relative retention times for methyldopa, carbidopa, and carbidopa related compound A are about 0.8, 1.0, and 1.8, respectively.]

Calculate the percentage of methyldopa in the portion of Carbidopa taken:

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

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

r_S = peak response of methyldopa from the *Impurity standard solution*

C_S = concentration of USP Methyldopa RS in the *Impurity standard solution* (µg/mL)

C_U = concentration of the *Sample solution* (µg/mL)

Calculate the percentage of carbidopa related compound A in the portion of Carbidopa taken:

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

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

r_S = peak response of carbidopa from the *Impurity standard solution*

C_S = concentration of USP Carbidopa RS in the *Impurity standard solution* (µg/mL)

C_U = concentration of the *Sample solution* (µg/mL)

Acceptance criteria: NMT 0.5% of methyldopa and NMT 0.5% of carbidopa related compound A

SPECIFIC TESTS

- **Optical Rotation, *Specific Rotation*⟨781S⟩**

Sample solution: 10 mg/mL in 0.7 g/mL of aluminum chloride solution (prepared using the hexahydrate form of the aluminum salt) that has been filtered and adjusted with 0.25 N sodium hydroxide to a pH of 1.5

Acceptance criteria: −21.0° to −23.5° calculated as the monohydrate

- **Loss on Drying ⟨731⟩**

Analysis: Heat 1 g in a suitable vacuum drying apparatus at 100° and a pressure of NMT 5 mm of mercury to constant weight. Cool, and weigh.

Acceptance criteria: 6.9%–7.9%

ADDITIONAL REQUIREMENTS

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

USP Carbidopa RS

USP Methyldopa RS

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

Topic/Question	Contact	Expert Committee
CARBIDOPA	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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