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Carbidopa and Levodopa Tablets

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click

<https://www.uspnf.com/rb-carbidopa-levodopa-tabs-20230929>.

DEFINITION

Carbidopa and Levodopa Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of carbidopa ($C_{10}H_{14}N_2O_4$) and levodopa ($C_9H_{11}NO_4$).

IDENTIFICATION

- **A.** The UV spectra of the carbidopa and levodopa peaks of *Sample solution A* and *Sample solution B*, respectively, correspond to those of the *Standard solution*, as obtained in the Assay.
- **B.** The retention times of the carbidopa and levodopa peaks of *Sample solution A* and *Sample solution B*, respectively, correspond to those of the *Standard solution*, as obtained in the Assay.

ASSAY

• PROCEDURE

Protect solutions containing carbidopa or levodopa from light and maintain them at 2°–8° until they are injected. Use within 12 h.

Buffer: 6 g/L of [anhydrous monobasic sodium phosphate](#) in [water](#), adjusted with [phosphoric acid](#) to a pH of 2.2

Mobile phase: [Alcohol](#) and *Buffer* (5:95)

Standard solution: 125 µg/mL of [USP Carbidopa RS](#) and 125 µg/mL of [USP Levodopa RS](#) in *Mobile phase*

System suitability solution: 2.5 µg/mL of [USP Levodopa Related Compound B RS](#) in *Standard solution*

Sample solution A: Nominally 125 µg/mL of carbidopa from Tablets prepared as follows. Transfer a suitable portion of powder from Tablets (NLT 10) to an appropriate volumetric flask. Add 80% of the total flask volume of *Mobile phase*. Sonicate for 15 min with intermittent shaking. Dilute with *Mobile phase*. Centrifuge the resulting solution and use the supernatant.

[NOTE—The use of a centrifuge speed of 3000 rpm for 5 min may be suitable.]

Sample solution B: Nominally 125 µg/mL of levodopa from *Sample solution A* in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 280 nm. For *Identification A*, use a diode array detector in the range of 210–400 nm.

Column: 4.6-mm × 15-cm; 5-µm packing [L1](#)

Autosampler temperature: 5°

Flow rate: 1 mL/min

Injection volume: 20 µL

Run time: NLT 5 times the retention time of carbidopa

System suitability

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

[NOTE—See [Table 1](#) for the relative retention times.]

Suitability requirements

Resolution: NLT 1.5 between levodopa related compound B and carbidopa, *System suitability solution*

Tailing factor: NMT 2.0 each for levodopa and carbidopa, *Standard solution*

Relative standard deviation: NMT 1.0% each for levodopa and carbidopa, *Standard solution*

Analysis

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

Calculate the percentage of the labeled amount of carbidopa ($C_{10}H_{14}N_2O_4$) in the portion of Tablets taken:

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

r_U = peak response of carbidopa from *Sample solution A*

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

C_s = concentration of [USP Carbidopa RS](#) in the *Standard solution* (µg/mL)

C_U = nominal concentration of carbidopa in *Sample solution A* (µg/mL)

Calculate the percentage of the labeled amount of levodopa ($C_9H_{11}NO_4$) in the portion of Tablets taken:

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

r_U = peak response of levodopa from *Sample solution B*

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

C_s = concentration of [USP Levodopa RS](#) in the *Standard solution* (µg/mL)

C_U = nominal concentration of levodopa in *Sample solution B* (µg/mL)

Acceptance criteria: 90.0%–110.0% of the labeled amount of carbidopa; 90.0%–110.0% of the labeled amount of levodopa

PERFORMANCE TESTS

Change to read:

- [DISSOLUTION \(711\)](#).

Test 1

Medium: 0.1 N [hydrochloric acid](#); 750 mL

Apparatus 1: 50 rpm

Time: 30 min

Diluent: 0.24 g/L of [sodium 1-decanesulfonate](#) in [water](#)

Mobile phase: 11.0 g/L of [monobasic sodium phosphate](#) in solution, prepared as follows. Transfer a sufficient quantity of [monobasic sodium phosphate](#) into a container, and dissolve in [water](#), using 95% of the total volume. Add 0.13% of the total volume of *Diluent*, and adjust with [phosphoric acid](#) to a pH of 2.8. Transfer to a suitable volumetric flask, and dilute with [water](#) to volume.

Standard solution: ($L_1/750$) mg/mL of [USP Levodopa RS](#) and ($L_2/750$) mg/mL of [USP Carbidopa RS](#) in *Medium*, where L_1 and L_2 are the label claims of levodopa and carbidopa, respectively, in mg/Tablet

Sample solution: A filtered portion of the solution under test

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Column: 3.9-mm × 30-cm; 10-µm packing [L1](#)

Flow rate: 2 mL/min

Injection volume: 20 µL

Run time: NLT 2 times the retention time for carbidopa

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for levodopa and carbidopa are 0.4 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 6 between levodopa and carbidopa

Relative standard deviation: NMT 2.0% for levodopa; NMT 2.0% for carbidopa

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of carbidopa ($C_{10}H_{14}N_2O_4$) and levodopa ($C_9H_{11}NO_4$) dissolved:

$$\text{Result} = (r_U/r_S) \times C_s \times V \times (1/L) \times 100$$

r_U = peak response of carbidopa or levodopa from the *Sample solution*

r_S = peak response of carbidopa or levodopa from the *Standard solution*

C_s = concentration of [USP Carbidopa RS](#) or [USP Levodopa RS](#) in the *Standard solution* (mg/mL)

V = volume of the *Medium*, 750 mL

L = label claim of carbidopa or levodopa (mg/Tablet)

Tolerances: NLT 80% (Q) of the labeled amount of carbidopa ($C_{10}H_{14}N_2O_4$) and levodopa ($C_9H_{11}NO_4$) are dissolved.

Test 2: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.

Medium: 0.1 N [hydrochloric acid](#); 750 mL

Apparatus 1: 100 rpm