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Carbidopa and Levodopa Orally Disintegrating Tablets

DEFINITION

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click www.uspnf.com/rb-carbidopa-levodopa-odt-20220429.

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

IDENTIFICATION

- **A.** The retention times of the major peaks of the *Sample solution* correspond to those of the *Standard solution*, as obtained in the Assay.

ASSAY

• PROCEDURE

Protect the volumetric solutions from light.

Buffer: 6.6 g/L of [monobasic sodium phosphate](#) in [water](#), adjusted with [phosphoric acid](#) to a pH of 2.2

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

Standard solution: 0.025 mg/mL of [USP Carbidopa RS](#) and 0.25 mg/mL of [USP Levodopa RS](#) in *Mobile phase*

Sample stock solution: Transfer NLT 10 Tablets to a 1-L volumetric flask. Add 750 mL of *Mobile phase*, sonicate for 20 min, and then stir for 20 min. Dilute with *Mobile phase* to volume.

Sample solution: Dilute the *Sample stock solution* with *Mobile phase* to obtain a nominal concentration of carbidopa of between 0.025 and 0.07 mg/mL and a nominal concentration of levodopa of 0.25 mg/mL.

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Column: 4.6-mm × 25-cm; 5-μm packing [L1](#)

Autosampler temperature: 6°

Flow rate: 1 mL/min

Injection volume: 20 μL

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for levodopa and carbidopa are 0.42 and 1.0, respectively.]

Suitability requirements

Tailing factor: NMT 2.4 for both the levodopa and carbidopa peaks

Relative standard deviation: NMT 2.0% for both carbidopa and levodopa

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amounts of carbidopa ($C_{10}H_{14}N_2O_4$) and 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 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)

C_U = nominal concentration of carbidopa or levodopa in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0% each of the labeled amounts of carbidopa and levodopa

PERFORMANCE TESTS

- [DISINTEGRATION \(701\)](#): NMT 60 s
- [DISSOLUTION \(711\)](#)

Test 1**Medium:** 0.1 N [hydrochloric acid](#); 750 mL**Apparatus 2:** 50 rpm**Time:** 10 min**Solution A:** 0.24 g/L of [sodium 1-decanesulfonate](#) in water**Mobile phase:** Dissolve 11.0 g of [monobasic sodium phosphate monohydrate](#) in 1 L of water. Add 1.3 mL of *Solution A*, and adjust with [phosphoric acid](#) to a pH of 2.8.**Standard solution:** ($L/800$) mg/mL each of [USP Carbidopa RS](#) and [USP Levodopa RS](#) in *Medium*, where L is the label claim in mg/Tablet of carbidopa or levodopa**Sample solution:** Pass a portion of the solution under test through a suitable filter of 0.45- μ m pore size, and discard the first 3 mL.**Chromatographic system**(See [Chromatography \(621\), System Suitability](#).)**Mode:** LC**Detector:** UV 280 nm**Column:** 4.6-mm $\times$ 15.0-cm; 5- μ m packing [L1](#)**Autosampler temperature:** 4°**Flow rate:** 2 mL/min**Injection volume:** 20 μ L**System suitability****Sample:** *Standard solution*

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

Suitability requirements**Tailing factor:** NMT 2.0 for both levodopa and carbidopa**Relative standard deviation:** NMT 2.0% for both levodopa and carbidopa**Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of the labeled amounts 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 75% (Q) of the labeled amount of carbidopa ($C_{10}H_{14}N_2O_4$) is dissolved, and NLT 75% (Q) of the labeled amount of levodopa ($C_9H_{11}NO_4$) is 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, degassed**Apparatus 2:** 75 rpm**Time:** 15 min**Solution A:** 0.24 g/L of [sodium 1-decanesulfonate](#) in [water](#)**Mobile phase:** 12.5 g/L of [monobasic sodium phosphate dihydrate](#) prepared as follows. Transfer an appropriate amount of [monobasic sodium phosphate dihydrate](#) to a suitable volumetric flask. Dissolve in 95% of the flask volume of [water](#). Add 0.13% of the flask volume of *Solution A*, and adjust with [phosphoric acid](#) to a pH of 2.8 ± 0.05 . Dilute with [water](#) to volume.**Standard stock solution 1:** 0.19 mg/mL of [USP Carbidopa RS](#) in *Medium*. Transfer an appropriate amount of [USP Carbidopa RS](#) to a suitable volumetric flask. Add about 60% of the flask volume of *Medium* and sonicate to promote dissolution. Allow the solution to cool to room temperature and dilute with *Medium* to volume.**Standard stock solution 2:** 1.1 mg/mL of [USP Levodopa RS](#) in *Medium*. Transfer an appropriate amount of [USP Levodopa RS](#) to a suitable volumetric flask. Add about 60% of the flask volume of *Medium* and sonicate to promote dissolution. Allow the solution to cool to room temperature and dilute with *Medium* to volume.**Standard solution****For Tablets labeled to contain 10 mg of carbidopa and 100 mg of levodopa:** 0.015 mg/mL of [USP Carbidopa RS](#) from *Standard stock solution 1* and 0.13 mg/mL of [USP Levodopa RS](#) from *Standard stock solution 2* in *Medium***For Tablets labeled to contain 25 mg of carbidopa and 100 or 250 mg of levodopa:** 0.038 mg/mL of [USP Carbidopa RS](#) from *Standard stock solution 1* and 0.22 mg/mL of [USP Levodopa RS](#) from *Standard stock solution 2* in *Medium***Sample solution:** Pass a portion of the solution under test through a suitable filter of 0.45- μ m pore size and discard the first 2 mL.**Chromatographic system**