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Amlodipine Besylate Tablets

DEFINITION

Change to read:

Amlodipine Besylate Tablets contain ▲an amount of amlodipine besylate equivalent to▲ (USP 1-May-2021) NLT 90% and NMT 110% of the labeled amount of amlodipine ($C_{20}H_{25}ClN_2O_5$).

IDENTIFICATION

Change to read:

- **A.** ▲The UV spectra of the major peak of the *Sample solution* correspond to those of the *Standard solution*, as obtained in the Assay.▲ (USP 1-May-2021)
- **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

Change to read:

• PROCEDURE

Buffer: Add 7.0 mL of [triethylamine](#) into a 1000-mL flask containing 900 mL of [water](#). Adjust the solution with [phosphoric acid](#) to a pH of 3.0.▲ (USP 1-May-2021) Dilute with [water](#) to volume, and mix well.

Mobile phase: [Methanol](#), [acetonitrile](#), and *Buffer* (35:15:50)

Standard solution: 0.0275 mg/mL of [USP Amlodipine Besylate RS](#) and 0.0025 mg/mL of [USP Amlodipine Related Compound A RS](#) in *Mobile phase*

Sample solution: Nominally 0.02 mg/mL of amlodipine in *Mobile phase* prepared as follows. Place Tablets (NLT 5) in a suitable volumetric flask, and add a sufficient quantity of *Mobile phase* to disintegrate the Tablets. Shake for 30 min, and dilute with *Mobile phase* to volume. Pass the sample through a syringe tip filter of 0.45-μm pore size. Discard the first few milliliters of the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 237 nm. ▲For *Identification A*, use a diode array detector in the range of 200–400 nm.▲ (USP 1-May-2021)

Column: 3.9-mm × 15-cm; ▲4- or▲ (USP 1-May-2021) 5-μm packing [L1](#)

Flow rate: 1 mL/min

Injection volume: 50 μL

Run time: NLT 3 times the retention ▲time▲ (USP 1-May-2021) of amlodipine

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for amlodipine related compound A and amlodipine are about 0.5 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 8.5 between amlodipine related compound A and amlodipine

Tailing factor: NMT 2.0 for amlodipine related compound A and amlodipine

Relative standard deviation: NMT 5.0% for amlodipine related compound A ▲and NMT 2.0% for amlodipine▲ (USP 1-May-2021)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of amlodipine ($C_{20}H_{25}ClN_2O_5$) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

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

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

C_S = concentration of [USP Amlodipine Besylate RS](#) in the *Standard solution* (mg/mL)

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

M_{r1} = molecular weight of amlodipine, 408.88

M_{r2} = molecular weight of amlodipine besylate, 567.05

Acceptance criteria: 90%–110% ▲▲ (USP 1-May-2021)

PERFORMANCE TESTS

Change to read:

• [DISSOLUTION \(711\)](#)

[NOTE—Do not expose any of the solutions to stainless steel because of the degradation of amlodipine.]

▲**Test 1**▲ (USP 1-May-2021)

Medium: [0.01 N hydrochloric acid](#); 500 mL

Apparatus 2: 75 rpm. [NOTE—Use paddles covered with Teflon or made of any inert material except stainless steel.]

Time: 30 min

Standard solution: ▲(L/360) mg/mL of [USP Amlodipine Besylate RS](#) in *Medium*, where L is the label claim of amlodipine in mg/Tablet. [NOTE—These solutions are stable for 1 day.]▲ (USP 1-May-2021)

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-μm pore size.

Blank: *Medium*

Instrumental conditions

Mode: UV

Analytical wavelength: 239 nm

Cell: 1-cm quartz

Analysis

Samples: *Standard solution* and *Sample solution*

▲▲ (USP 1-May-2021)

Calculate the percentage of the labeled amount of amlodipine ($C_{20}H_{25}ClN_2O_5$) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times V \times \text{▲▲ (USP 1-May-2021)} \times (M_{r1}/M_{r2}) \times (1/L) \times 100$$

A_U = absorbance of amlodipine from the *Sample solution*

A_S = absorbance of amlodipine from the *Standard solution*

C_S = concentration of ▲[USP Amlodipine Besylate RS](#)▲ (USP 1-May-2021) in the *Standard solution* (mg/mL)

V = volume of *Medium*, 500 mL

▲▲ (USP 1-May-2021)

M_{r1} = molecular weight of amlodipine, 408.88

M_{r2} = molecular weight of amlodipine besylate, 567.05

L = label claim (mg/Tablet)

Tolerances: NLT 75% (Q) of the labeled amount of amlodipine ($C_{20}H_{25}ClN_2O_5$) is dissolved.

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

Medium, Apparatus 2, and Time: Proceed as directed in *Test 1*.

Buffer A: Dissolve 1.36 g of [potassium phosphate, monobasic](#) in 1000 mL of [water](#). Add 5 mL of [triethylamine](#) and adjust the solution with [phosphoric acid](#) to a pH of 2.0.

Buffer B: Dilute 7.0 mL of [triethylamine](#) in 1000 mL of [water](#). Adjust the solution with [phosphoric acid](#) to a pH of 3.0.

Mobile phase: [Acetonitrile](#) and *Buffer A* (30:70)

Diluent: [Acetonitrile](#), [methanol](#), and *Buffer B* (15:35:50)

Standard stock solution: 0.693 mg/mL of [USP Amlodipine Besylate RS](#) in *Diluent*

Standard solution: (L/361) mg/mL of [USP Amlodipine Besylate RS](#) in *Medium*, where L is the label claim of amlodipine in mg/Tablet

Sample solution: Centrifuge a portion of the solution under test for 5 min.

Chromatographic system

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

Mode: LC

Detector: UV 237 nm

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