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Amlodipine and Benazepril Hydrochloride Capsules

DEFINITION

Amlodipine and Benazepril Hydrochloride Capsules contain an amount of amlodipine besylate equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of amlodipine ($C_{20}H_{25}N_2O_5Cl$) and NLT 90.0% and NMT 110.0% of the labeled amount of benazepril hydrochloride ($C_{24}H_{28}N_2O_5 \cdot HCl$).

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*
- **B.** The UV spectra of the major peaks of the *Sample solution* correspond to those of the *Standard solution*, as obtained in the *Assay*.

ASSAY

Change to read:

- **Procedure**

Buffer 1: 0.7% (v/v) triethylamine in water. Adjust with phosphoric acid to a pH of 3.0, and add 1.2 g/L of ▲tetrabutylammonium▲ (ERR-1-Oct-2024) hydrogen sulfate to this solution.

Buffer 2: 0.7% (v/v) triethylamine in water. Adjust with phosphoric acid to a pH of 3.0.

Mobile phase: Acetonitrile, methanol, and *Buffer 1* (10:30:70)

Diluent: Acetonitrile, methanol, and *Buffer 2* (20:30:50)

Standard solution: Concentrations of USP Amlodipine Besylate RS and USP Benazepril Hydrochloride RS in *Diluent* as directed in *Table 1*.

Table 1

Strength of Capsule Amlodipine/Benazepril Hydrochloride (mg/mg)	Concentration of USP Amlodipine Besylate RS/ USP Benazepril Hydrochloride RS (mg/mL)
2.5/10	0.18/0.5
5/20	0.18/0.5
5/10	0.18/0.25
10/20	0.36/0.5
5/40 and 10/40	0.056/0.16

Sample solution: Transfer the contents of 5 Capsules into a suitable volumetric flask to obtain nominal concentrations as given in *Table 2*. Add *Diluent* to about 70% of the volume of the flask and keep on a rotary shaker for about 45 min, sonicate for about 30 min with occasional shaking, and dilute with *Diluent* to volume. Centrifuge a portion of the solution for about 10 min, and pass through a filter of 0.45-µm pore size.

Table 2

Strength of Capsule Amlodipine/Benazepril Hydrochloride (mg/mg)	Nominal Concentration of Amlodipine/Benazepril Hydrochloride (mg/mL)
2.5/10	0.125/0.5
5/20	0.125/0.5

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Strength of Capsule Amlodipine/Benazepril Hydrochloride (mg/mg)	Nominal Concentration of Amlodipine/Benazepril Hydrochloride (mg/mL)
5/10	0.125/0.25
10/20	0.25/0.5
5/40	0.02/0.16
10/40	0.04/0.16

Chromatographic system

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

Mode: LC

Detector: UV 237 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.

Column: 4.6-mm × 15-cm; 5-µm packing L1

Flow rate: 1.2 mL/min

Injection volume: 10 µL

Run time: NLT 2 times the retention time of amlodipine

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0 for the amlodipine and benazepril peaks

Relative standard deviation: NMT 2.0% for the amlodipine and benazepril peaks

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of amlodipine ($C_{20}H_{25}N_2O_5Cl$) in the portion of Capsules 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

Calculate the percentage of the labeled amount of benazepril hydrochloride ($C_{24}H_{28}N_2O_5 \cdot HCl$), in the portion of Capsules taken:

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

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

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

C_S = concentration of USP Benazepril Hydrochloride RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: 0.01 N hydrochloric acid; 500 mL

Apparatus 1: 100 rpm

Time: 30 min

Buffer: 2.72 g/L of potassium phosphate, monobasic in water. Add 0.2% (v/v) triethylamine per liter. Adjust with phosphoric acid to a pH of 3.0.

Mobile phase: Acetonitrile, methanol, and *Buffer* (15:35:50)

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