Amlodipine Besylate Tablets

**DEFINITION**

Amlodipine Besylate Tablets contain NLT 90% and NMT 110% of the labeled amount of amlodipine (C$_{20}$H$_{25}$N$_{2}$O$_{5}$Cl).

**IDENTIFICATION**

- **A. ULTRAVIOLET ABSORPTION (197U)**

  **Standard solution** and **Sample solution**: Prepare as directed in the test for **Dissolution**.

  **Acceptance criteria**: Meet the requirements

- **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**: 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 ± 0.1. Dilute with water to volume, and mix well.

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

  **System suitability solution**: 0.02 mg/mL of USP Amlodipine Besylate RS and 0.002 mg/mL of USP Amlodipine Related Compound A RS in Mobile phase

  **Standard solution**: 0.02 mg/mL of amlodipine prepared from USP Amlodipine Besylate RS in Mobile phase

  **Sample stock solution**: Place 5 Tablets into a 500-mL volumetric flask. Add 50 mL of Mobile phase to the flask, and swirl to disintegrate the Tablets. Add 300 mL of Mobile phase, insert the stopper into the flask, and shake on a reciprocating shaker for 30 min. Dilute with Mobile phase to volume, and mix well.

  **Sample solution**: 0.02 mg/mL of amlodipine from the Sample stock solution in Mobile phase. Pass the sample through a syringe tip filter of 0.45-µm pore size.

  **Chromatographic system**

  (See Chromatography (621). System Suitability.)

  **Mode**: LC

  **Detector**: UV 237 nm

  **Column**: 3.9-mm × 15-cm; 5-µm packing L1

  **Flow rate**: 1 mL/min

  **Injection size**: 50 µL

  **System suitability**

  **Sample**: System suitability solution

  [NOTE—The run time is about three times the retention of the amlodipine peak.]

  **Suitability requirements**

  **Resolution**: NLT 8.5 between amlodipine and amlodipine related compound A

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

  **Relative standard deviation**: NMT 1.0% for amlodipine and NMT 5.0% for amlodipine related compound A

  **Analysis**

  **Samples**: Standard solution and Sample solution

  Calculate the percentage of the labeled amount of amlodipine (C$_{20}$H$_{25}$N$_{2}$O$_{5}$Cl) in the portion of Tablets taken:

  Result = (r$_{1}$/r$_{0}$) × (C$_{i}$/C$_{0}$) × 100

  r$_{0}$ = peak response of Sample solution

  r$_{1}$ = peak response of Sample solution

  C$_{i}$ = concentration of Sample solution (mg/mL)

  C$_{0}$ = nominal concentration of amlodipine in the Sample solution (mg/mL)

  **Acceptance criteria**: 90%–110% of the labeled amount of amlodipine (C$_{20}$H$_{25}$N$_{2}$O$_{5}$Cl)

**IMPURITIES**

- **ORGANIC IMPURITIES**

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

  **Standard solution**: Use the System suitability solution.

  **Sample solution**: Place a suitable number of Tablets into a 25-mL volumetric flask to obtain a solution having a final nominal concentration of 0.4 mg/mL of amlodipine. Add about 10 mL of Mobile phase to the flask. Swirl to disintegrate the Tablets, follow by sonication for 5 min to completely dissolve, and then cool the sample to room temperature. Dilute with Mobile phase to volume. Stir for an additional 15 min using a magnetic stir bar, and pass the sample through a syringe tip filter of 0.45-µm pore size, discarding the first 5 mL.

  **Analysis**

  **Samples**: Standard solution and Sample solution

  Calculate the percentage of amlodipine related compound A in the portion of Tablets taken:

  Result = (r$_{1}$/r$_{0}$) × (C$_{i}$/C$_{0}$) × (M$_{1}$/M$_{2}$) × V × 100

  r$_{0}$ = peak response of amlodipine related compound A from the Sample solution

  r$_{1}$ = peak response of amlodipine related compound A from the Standard solution

  C$_{i}$ = concentration of USP Amlodipine Related Compound A RS in the Standard solution (mg/mL)

  C$_{0}$ = nominal concentration of amlodipine in the Sample solution (mg/mL)

  M$_{1}$ = molecular weight of amlodipine (C$_{20}$H$_{25}$N$_{2}$O$_{5}$Cl) 567.06

  M$_{2}$ = molecular weight of amlodipine related compound A fumarate, 522.93

  V = volume of Medium, 500 mL

  **Tolerances**: NLT 75% (Q) of the labeled amount of amlodipine (C$_{20}$H$_{25}$N$_{2}$O$_{5}$Cl) is dissolved.

- **UNIFORMITY OF DOSAGE UNITS (905)**

  Meet the requirements

**PERFORMANCE TESTS**

- **Dissolution (711)**

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

Aromatic Ammonia Spirit

Aromatic Ammonia Spirit is a hydroalcoholic solution that contains, in each 100 mL, not less than 1.7 g and not more than 2.1 g of total NH₃, and Ammonium Carbonate corresponding to not less than 3.5 g and not more than 4.5 g of (NH₄)₂CO₃.