

Calculate the percentage of amlodipine glucose/galactose adduct or amlodipine lactose adduct, if present, 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 the amlodipine glucose/galactose adduct or amlodipine lactose adduct in the *Sample solution*
 r_S = peak response of amlodipine in 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, 408.9
 M_{r2} = molecular weight of amlodipine besylate, 567.05

Calculate the percentage of any other individual unspecified degradation product in the portion of Tablets taken:

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

- r_U = peak response of each impurity from the *Sample solution*
 r_S = peak response of amlodipine from the *Standard solution*
 C_S = concentration of amlodipine in the *Standard solution* (mg/mL)
 C_U = nominal concentration of amlodipine in the *Sample solution* (mg/mL)

Acceptance criteria: See Table 1.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Amlodipine related compound A ^a	0.50	1.0
Amlodipine lactose adduct ^b	0.80	0.5
Amlodipine glucose/galactose adduct ^b	0.90	0.5
Amlodipine besylate	1.0	—
Any other individual unspecified degradation product	—	0.20

^a 3-Ethyl, 5-methyl [2-(2-aminoethoxymethyl)-4-(2-chlorophenyl)-6-methyl-3,5-pyridinedicarboxylate].

^b Formulation-specific impurities.

ADDITIONAL REQUIREMENTS

- PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers. Store at controlled room temperature.
- USP REFERENCE STANDARDS** (11)
 - USP Amlodipine Besylate RS
 - USP Amlodipine Related Compound A RS
 - 3-Ethyl, 5-methyl [2-(2-aminoethoxymethyl)-4-(2-chlorophenyl)-6-methyl-3,5-pyridinedicarboxylate fumarate].
 $C_{20}H_{23}ClN_2O_5 \cdot C_4H_4O_4$ 522.93

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 NH_3 , and Ammonium Carbonate corresponding to not less than 3.5 g and not more than 4.5 g of $(NH_4)_2CO_3$.

Packaging and storage—Preserve in tight, light-resistant containers, at a temperature not exceeding 30 °.

Alcohol content, Method I (611): between 62.0% and 68.0% of C_2H_5OH .

Assay for total NH_3 —Transfer 10.0 mL to a 250-mL conical flask containing about 50 mL of water. Add 30.0 mL of 0.5 N sulfuric acid VS, and boil until the solution becomes clear. Cool, add methyl red TS, and titrate the excess acid with 0.5 N sodium hydroxide VS. Perform a blank determination (see *Residual Titrations* under *Titrimetry* (541)). Each mL of 0.5 N sulfuric acid is equivalent to 8.515 mg of NH_3 .

Assay for ammonium carbonate—Transfer 10.0 mL to a flask of about 300-mL capacity. Add 30 mL of 0.5 N sodium hydroxide, and boil the mixture, replacing the water lost by evaporation, until the vapors no longer turn moistened red litmus paper blue. Cool, dilute with 100 mL of cold, carbon dioxide-free water, add about 6 drops of phenolphthalein TS, then add just enough 0.5 N sulfuric acid VS to discharge the color of the phenolphthalein. Add methyl orange TS, and titrate with 0.5 N sulfuric acid VS. Perform a blank determination (see *Residual Titrations* under *Titrimetry* (541)). Each mL of 0.5 N sulfuric acid consumed in the titration with methyl orange TS is equivalent to 48.04 mg of $(NH_4)_2CO_3$.

Ammonium Chloride

NH_4Cl 53.49

Ammonium chloride.

Ammonium chloride [12125-02-9].

» Ammonium Chloride contains not less than 99.5 percent and not more than 100.5 percent of NH_4Cl , calculated on the dried basis.

Packaging and storage—Preserve in tight containers.

Identification—A solution (1 in 10) responds to the tests for *Ammonium* (191) and for *Chloride* (191).

pH (791): between 4.6 and 6.0, in a solution (1 in 20).

Loss on drying (731)—Dry it over silica gel for 4 hours: it loses not more than 0.5% of its weight.

Residue on ignition (281)—Add 1 mL of sulfuric acid to about 2 g, accurately weighed, and heat the mixture gently until volatilization is complete: the residue is white, and when ignited, not more than 0.1% of nonvolatile substance remains.

Limit of thiocyanate—Acidify 10 mL of a solution (1 in 10) with hydrochloric acid, and add a few drops of ferric chloride TS: no orange-red color is produced.

Heavy metals, Method I (231): 0.001%.

Assay—Transfer about 100 mg of Ammonium Chloride, accurately weighed, to a conical flask, add 10 mL of water, and swirl to dissolve. Add 10 mL of glacial acetic acid, 75 mL of methanol, and 0.5 mL of eosin Y TS. Titrate, with shaking, with 0.1 N silver nitrate VS to a pink endpoint. Each mL of 0.1 N silver nitrate is equivalent to 5.349 mg of NH_4Cl .

Ammonium Chloride Injection

» Ammonium Chloride Injection is a sterile solution of Ammonium Chloride in Water for Injection. It contains not less than 95.0 percent and not more than 105.0 percent of the labeled amount of NH_4Cl . Hydrochloric acid may be added to adjust the pH.

Packaging and storage—Preserve in single-dose or multiple-dose containers, preferably of Type I or Type II glass.