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Amlodipine Compounded Oral Suspension

DEFINITION
Amlodipine Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of amlodipine ($C_{20}H_{25}ClN_2O_5$).

Prepare Amlodipine Compounded Oral Suspension 1 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

Amlodipine besylate tablets[a] equivalent to	100 mg of amlodipine
Vehicle: a 1:1 mixture of Ora-Sweet[b] and Ora-Plus,[b] a sufficient quantity to make	100 mL

[a] Norvasc 5-mg tablets, Pfizer, Inc., Groton, CT.

[b] Paddock Laboratories, Minneapolis, MN.

Calculate the required quantity of each ingredient for the total amount to be prepared. Place the required number of tablets in a suitable mortar and comminute to a fine powder. Add the *Vehicle* in small portions, and triturate to make a smooth paste. Add increasing volumes of the *Vehicle* to make an amlodipine liquid that is pourable. Transfer the contents of the mortar, stepwise and quantitatively, to a calibrated bottle. Add enough of the *Vehicle* to bring to final volume, and mix well. [Note—To ensure component uniformity, homogenization is recommended.]

ASSAY

• **Procedure**

Mobile phase: Acetonitrile, methanol, and 40 mM ammonium acetate (50:15:35). Filter through a nylon 66 filter of 0.45-µm pore size, and degas.

Standard stock solution: Dissolve an appropriately weighed amount of USP Amlodipine Besylate RS in methanol, equivalent to 1.0 mg/mL of amlodipine (approximately equal to 1.4 mg/mL of amlodipine besylate).

Standard solution: Transfer 1.0 mL of the *Standard stock solution* into a 50-mL volumetric flask, and dilute with *Mobile phase* to volume to obtain a solution with a nominal concentration of about 20 µg/mL of amlodipine. Centrifuge.

Sample solution: Shake thoroughly by hand each bottle of Oral Suspension. Pipet 1.0 mL of Oral Suspension into a 50-mL volumetric flask, rinse the pipet three times with *Mobile phase*, and dilute with *Mobile phase* to volume to obtain a solution with a nominal concentration of about 20 µg/mL of amlodipine. Centrifuge.

Chromatographic system

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

Mode: LC

Detector: UV 240 nm

Column: 3.0-mm × 15-cm; 5-µm packing L10

Flow rate: 0.4 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for amlodipine is about 10.1 min.]

Suitability requirements

Column efficiency: NLT 4000 theoretical plates

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% for replicate injections

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 Oral Suspension taken:

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

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

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

C_S = concentration of amlodipine in the *Standard solution* (µg/mL)

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 4.0–5.0

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistant containers. Store in a refrigerator or at controlled room temperature.

• **Beyond-Use Date:** NMT 90 days after the date on which it was compounded when stored in a refrigerator; NMT 60 days when stored at controlled room temperature

• **Labeling:** Label it to indicate that it is to be well shaken before use, and to state the *Beyond-Use Date*.

• **USP Reference Standards** ⟨11⟩
USP Amlodipine Besylate RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
AMLODIPINE COMPOUNDED ORAL SUSPENSION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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