

Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-Sep-2023
Document Type: USP Monographs
DocId: GUID-D445FC16-19FB-4CDE-85DB-CB8B89C22450_4_en-US
DOI: https://doi.org/10.31003/USPNF_M1045_04_01
DOI Ref: 4b2y5

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Fosamprenavir Calcium Tablets

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click www.uspnf.com/rb-fosamprenavir-calcium-tabs-20230825.

DEFINITION

Fosamprenavir Calcium Tablets contain an amount of fosamprenavir calcium ($C_{25}H_{34}CaN_3O_9PS$) equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of fosamprenavir ($C_{25}H_{34}N_3O_9PS$).

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197M or 197K
- **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: 4.68 g/L of [monobasic sodium phosphate dihydrate](#) in [water](#). Add 1.5 mL of [phosphoric acid](#) per 1 L of this solution.

Mobile phase: [Acetonitrile](#) and *Buffer* (35:65)

Diluent: [Acetonitrile](#) and *Buffer* (20:80)

Standard solution: 0.26 mg/mL of [USP Fosamprenavir Calcium RS](#) in *Diluent*. Sonicate to dissolve prior to final dilution, if necessary.

Sample solution: Nominally 0.28 mg/mL of fosamprenavir from Tablets in *Diluent* prepared as follows. Transfer an amount equivalent to 14 mg of fosamprenavir from finely powdered Tablets (NLT 20) to a 50-mL volumetric flask. Add about 40 mL of *Diluent* and sonicate to dissolve, if necessary. Dilute with *Diluent* to volume. Pass a portion of the solution through a suitable filter, and discard the first few milliliters of the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 266 nm

Column: 4.6-mm x 15-cm; 3.5- μ m packing [L1](#)

Column temperature: 40°

Flow rate: 1.5 mL/min

Injection volume: 10 μ L

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of fosamprenavir ($C_{25}H_{34}N_3O_9PS$) 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 fosamprenavir from the *Sample solution*

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

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

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

M_{r1} = molecular weight of fosamprenavir, 585.61

M_{r2} = molecular weight of fosamprenavir calcium, 623.67

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS**Change to read:**

- [DISSOLUTION \(711\)](#).

▲Test 1▲ (RB 1-Sep-2023)

Medium: ▲0.02 M [sodium acetate](#) buffer, pH 3.5, prepared as follows. Dissolve 2.67 g of [sodium acetate](#) in 100 mL of [water](#). Add 13.3 mL of [glacial acetic acid](#) and then dilute with [water](#) to 1000 mL; 900 mL.▲ (ERR 1-Sep-2023)

Apparatus 2: 75 rpm

Time: 30 min

Standard solution: 0.83 mg/mL of [USP Fosamprenavir Calcium RS](#) in *Medium*. Sonicate to dissolve prior to final dilution, if necessary.

Sample solution: Pass a portion of the solution under test through a suitable filter.

Instrumental conditions

Mode: UV

Analytical wavelength: 263 nm

Cell path length: 0.02 cm

Blank: *Medium*

System suitability

Sample: *Standard solution*

Suitability requirement

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution and Sample solution*

Calculate the percentage of the labeled amount of fosamprenavir ($C_{25}H_{34}N_3O_9PS$) dissolved:

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

A_U = absorbance from the *Sample solution*

A_S = absorbance from the *Standard solution*

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

V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)

M_{r1} = molecular weight of fosamprenavir, 585.61

M_{r2} = molecular weight of fosamprenavir calcium, 623.67

Tolerances: NLT 80% (Q) of the labeled amount of fosamprenavir ($C_{25}H_{34}N_3O_9PS$) is dissolved.

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

Solution A: 10 N acetic acid solution prepared as follows. Dilute 145 mL of [glacial acetic acid](#) to 250 mL with [water](#).

Medium: 0.25 M [sodium acetate](#) buffer, pH 3.5, prepared as follows. Dissolve 34 g of [sodium acetate](#) in 500 mL of [water](#). Add 300 mL of *Solution A*. Adjust with *Solution A* if necessary to a pH of 3.5 and then dilute with [water](#) to 1000 mL; 900 mL, deaerated

Apparatus 2: 75 rpm

Time: 30 min

Solution B: [Methanol](#) and [acetonitrile](#) (60:40)

Buffer: Dissolve 3.14 g of [ammonium formate](#) in 1000 mL of [water](#). Adjust with [formic acid](#) to a pH of 3.2.

Mobile phase: *Solution B* and *Buffer* (60:40)

Solution C: 1.5 mL/L of [phosphoric acid](#) in [water](#)

Diluent: [Acetonitrile](#) and *Solution C* (55:45)

Standard stock solution: 0.5 mg/mL of [USP Fosamprenavir Calcium RS](#) in *Diluent*. Sonicate to dissolve.

Standard solution: 0.1 mg/mL of [USP Fosamprenavir Calcium RS](#) from *Standard stock solution* in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size. Dilute with *Medium* to a concentration that is similar to that of the *Standard solution*.

Chromatographic system

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

Mode: LC

Detector: UV 266 nm

Column: 4.6-mm × 25-cm; 5-µm packing [L7](#)

Temperatures

Autosampler: 10°

Column: 30°