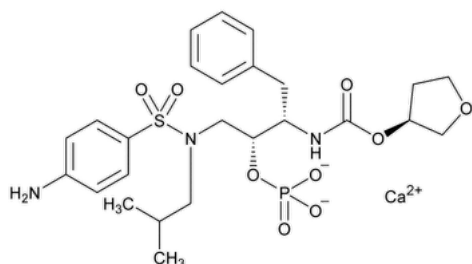


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Fosamprenavir Calcium

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$C_{25}H_{34}CaN_3O_9PS$ 623.67

Carbamic acid, [(1S,2R)-3-[[[(4-aminophenyl)sulfonyl](2-methylpropyl)amino]-1-(phenylmethyl)-2-(phosphonoxy)propyl]-C-[(3S)-tetrahydro-3-furyl] ester, calcium salt (1:1);

(3S)-Tetrahydro-3-furyl [(αS)-α-[(1R)-1-hydroxy-2-(N¹-isobutylsulfanilamido)ethyl]phenethyl]carbamate, calcium phosphate (ester) (1:1);

Calcium (2R,3S)-1-[(4-amino-N-isobutylphenyl)sulfonamide]-4-phenyl-3-[[[(S)-tetrahydrofuran-3-yl]oxy]carbonyl]amino]butan-2-yl phosphate. CAS RN®: 226700-81-8; UNII: ID1GU2627N.

DEFINITION

Fosamprenavir Calcium contains NLT 98.0% and NMT 102.0% of fosamprenavir calcium ($C_{25}H_{34}CaN_3O_9PS$), calculated on the anhydrous and solvent-free basis.

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.
- **C. IDENTIFICATION TESTS—GENERAL (191), Chemical Identification Tests, Calcium:** Meets the requirements

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: 0.26 mg/mL of Fosamprenavir Calcium in *Diluent*. Sonicate to dissolve prior to final dilution, if necessary.

Chromatographic system

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

Mode: LC

Detector: UV 266 nm

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

Column temperature: 40°

Flow rate: 1.5 mL/min

Injection volume: 10 μL

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 fosamprenavir calcium ($C_{25}H_{34}CaN_3O_9PS$) in the portion of Fosamprenavir Calcium taken:

$$\text{Result} = (r_u/r_s) \times (C_s/C_u) \times 100$$

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 = concentration of Fosamprenavir Calcium in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the anhydrous and solvent-free basis

IMPURITIES

• ORGANIC IMPURITIES: EARLY-ELUTING IMPURITIES

Buffer, Mobile phase, Diluent, Sample solution, and Chromatographic system: Proceed as directed in the Assay.

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

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

System suitability

Samples: *System suitability solution* and *Standard solution*

Suitability requirements

Resolution: NLT 1.5 between fosamprenavir pyrophosphate and fosamprenavir *n*-propyl homolog, *System suitability solution*

Relative standard deviation: NMT 5.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of any individual early-eluting impurity in the portion of Fosamprenavir Calcium taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

r_U = peak response of any individual impurity 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 = concentration of Fosamprenavir Calcium in the *Sample solution* (mg/mL)

F = relative response factor (see [Table 1](#))

Acceptance criteria: See [Table 1](#). The reporting threshold is 0.03%.

Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Fosamprenavir amine ^a	0.4	1.0	0.3
Fosamprenavir pyrophosphate ^b	0.7	0.77	0.2
Fosamprenavir <i>n</i> -propyl homolog ^c	0.8	1.0	0.3
Fosamprenavir	1.0	1.0	—
Any unspecified impurity ^d	—	1.0	0.05
Total impurities ^e	—	—	1.3

^a (2*R*,3*S*)-3-Amino-1-[(4-amino-*N*-isobutylphenyl)sulfonamide]-4-phenylbutan-2-yl dihydrogen phosphate.

^b (S)-Tetrahydrofuran-3-yl {(2*S*,3*R*)-4-[(4-amino-*N*-isobutylphenyl)sulfonamide]-3-[(hydroxy(phosphonooxy)phosphoryl)oxy]-1-phenylbutan-2-yl}carbamate.

^c Calcium (2*R*,3*S*)-1-[(4-amino-*N*-propylphenyl)sulfonamide]-4-phenyl-3-[[[(S)-tetrahydrofuran-3-yl]oxy]carbonyl]amino]butan-2-yl phosphate.

^d Exclude any individual unspecified impurity that elutes after fosamprenavir.