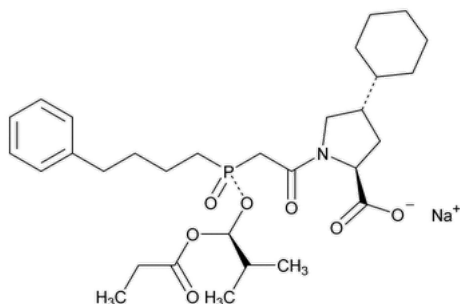


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Fosinopril Sodium



$C_{30}H_{45}NNaO_7P$ 585.64

L-Proline, 4-cyclohexyl-1-[[[2-methyl-1-(1-oxopropoxy)propoxy](4-phenylbutyl)phosphinyl]acetyl]-, sodium salt, [1[S*(R*)],2 α ,4 β]-;
 (4S)-4-Cyclohexyl-1-[(R)-[(S)-1-hydroxy-2-methylpropoxy](4-phenylbutyl)phosphinyl]acetyl-L-proline propionate (ester), sodium salt CAS RN®:
 88889-14-9; UNII: NW2RTH6T2N.

DEFINITION

Fosinopril Sodium contains NLT 97.5% and NMT 102.0% of fosinopril sodium ($C_{30}H_{45}NNaO_7P$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 197A or 197M ▲ (CN 1-May-2020)
- **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

Mobile phase: [Acetonitrile](#), [phosphoric acid](#), and [water](#) (2000:1:10)

System suitability solution: 0.1 mg/mL of [USP Fosinopril Sodium RS](#) and 0.01 mg/mL of [USP Fosinopril Related Compound B RS](#) in *Mobile phase*

Standard solution: 0.10 mg/mL of [USP Fosinopril Sodium RS](#) in *Mobile phase*

Sample solution: 0.10 mg/mL of Fosinopril Sodium in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 214 nm

Column: 3.9-mm × 15-cm; 5- μ m packing [L3](#)

Column temperature: 33°

Flow rate: 1.2 mL/min

Injection volume: 20 μ L

Run time: NLT 4 times the retention time of the fosinopril peak

System suitability

Sample: *System suitability solution*

Suitability requirements

Resolution: NLT 2.0 between fosinopril related compound B and fosinopril

Relative standard deviation: NMT 0.73% for the fosinopril peak

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of fosinopril sodium ($C_{30}H_{45}NNaO_7P$) in the portion of Fosinopril Sodium taken:

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

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

r_s = peak response of fosinopril from the *Standard solution*

C_s = concentration of [USP Fosinopril Sodium RS](#) in the *Standard solution* (mg/mL)

C_u = concentration of Fosinopril Sodium in the *Sample solution* (mg/mL)

Acceptance criteria: 97.5%–102.0% on the anhydrous basis

IMPURITIES

• ORGANIC IMPURITIES, PROCEDURE 1

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

System suitability solution: 0.1 mg/mL of [USP Fosinopril Sodium RS](#) and 0.01 mg/mL each of [USP Fosinopril Related Compound A RS](#) and [USP Fosinopril Related Compound B RS](#) in *Mobile phase*

Analysis

Sample: *Sample solution*

Calculate the percentage of each individual related compound in the portion of Fosinopril Sodium taken:

$$\text{Result} = (r_u/r_T) \times 100$$

r_u = individual peak response, other than the fosinopril peak

r_T = sum of all the peak responses

Acceptance criteria See [Table 1](#).

Table 1

Name	Relative Retention Time	Procedure	Acceptance Criteria, NMT (%)
Impurity 3 (if present) ^a	0.37	1	0.15
Impurity 1 ^b	0.53	1	0.3
Impurity 2 ^c	0.67	1	0.2
Fosinopril related compound B ^d	0.7	1	1.0
Fosinopril related compound E ^e	0.8	3	0.3
Fosinopril related compound F ^f	0.9	3	0.3
Fosinopril related compound C ^g	1.2	2	0.3
Fosinopril related compound D ^h	1.3	2	0.3
Fosinopril related compound A ⁱ	2.0	1	0.75
Any individual unspecified impurity	—	1	0.1