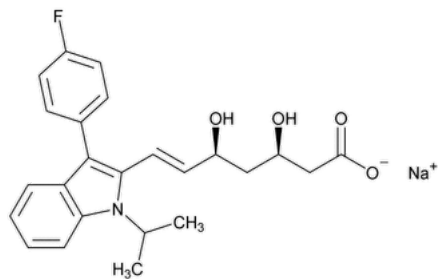


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Fluvastatin Sodium



$C_{24}H_{25}FNNaO_4$ 433.45
6-Heptenoic acid, 7-[3-(4-fluorophenyl)-1-(1-methyl ethyl)-1H-indol-2-yl]-3,5-dihydroxy-, monosodium salt, [*R**,*S**-(*E*)]-(±)-;
Sodium (±)-(3*R**,5*S**,6*E*)-7-[3-(*p*-fluorophenyl)-1-iso propylindol-2-yl]-3,5-dihydroxy-6-heptenoate CAS RN®: 93957-55-2; UNII: PYF7O1FV7F.

DEFINITION

Fluvastatin Sodium contains NLT 98.0% and NMT 102.0% of fluvastatin sodium ($C_{24}H_{25}FNNaO_4$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

- **A.** **SPECTROSCOPIC IDENTIFICATION TESTS** (197), *Infrared Spectroscopy*: 197A or 197K▲ (CN 1-May-2020)

If a difference appears in the IR spectra of the analyte and the Standard, dissolve equal portions of the sample specimen and the USP Reference Standard in equal volumes of [methanol](#). Evaporate the solutions to dryness on a steam bath, protecting the solutions from light, and dry at 105° for 30 min. Repeat the test on the residues.

- **B.** **IDENTIFICATION TESTS—GENERAL** (191), *Chemical Identification Tests, Sodium*: Meets the requirements of test A
- **C.** 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

Solution A: Add 20 mL of 25% aqueous [tetramethylammonium hydroxide](#) solution to 880 mL of [water](#). Adjust with about 2.3 mL of [phosphoric acid](#) to a pH of 7.2 ± 0.2. Add 100 mL of a mixture of [methanol](#) and [acetonitrile](#) (60:40).

Solution B: Add 20 mL of 25% aqueous [tetramethylammonium hydroxide](#) solution and 80 mL of [water](#) to 900 mL of a mixture of [methanol](#) and [acetonitrile](#) (60:40). Adjust with about 2.3 mL of [phosphoric acid](#) to a pH of 7.2 ± 0.2.

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	60	40
6	60	40
20	18	82
20.1	60	40
25.1	60	40

System suitability solution: 0.5 mg/mL of fluvastatin sodium from [USP Fluvastatin for System Suitability RS](#), dissolved first in *Solution B*, using 40% of the final volume, then diluted with *Solution A* to volume

Standard solution: 0.5 mg/mL of [USP Fluvastatin Sodium RS](#), dissolved first in *Solution B*, using 40% of the final volume, then diluted with *Solution A* to volume

Sample solution: 0.5 mg/mL of Fluvastatin Sodium, dissolved first in *Solution B*, using 40% of the final volume, then diluted with *Solution A* to volume

Chromatographic system

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

Mode: LC

Detector: UV 305 nm

Column: 4.6-mm × 5-cm; 5-μm packing [L1](#)

Column temperature: 35°

Flow rate: 3 mL/min

Injection volume: 20 μL

[NOTE—Adjust the start time of the gradient step and the equilibration time for each instrument.]

System suitability

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

[NOTE—The relative retention times for fluvastatin and fluvastatin *anti*-isomer are about 1.0 and 1.2, respectively.]

Suitability requirements

Resolution: NLT 1.6 between fluvastatin *anti*-isomer and fluvastatin, *System suitability solution*

Tailing factor: NMT 3.0 for the fluvastatin peak, *System suitability solution*

Relative standard deviation: NMT 0.73%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of fluvastatin sodium ($C_{24}H_{25}FNNaO_4$) in the portion of Fluvastatin Sodium taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

C_U = concentration of Fluvastatin Sodium in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the anhydrous basis

IMPURITIES

• ORGANIC IMPURITIES

[NOTE—Protect all solutions from light, and use amber autosampler vials and low-actinic glassware.]

Solution A, Solution B, Mobile phase, Standard solution, and Sample solution: Prepare as directed in the Assay.

System suitability solution A: Prepare as directed for the *System suitability solution* in the Assay.

System suitability solution B: 0.1 mg/mL of [USP Fluvastatin Related Compound B RS](#) in a mixture of [methanol](#) and [acetonitrile](#) (60:40).

Transfer about 0.5 mL of this solution to a 10-mL volumetric flask, and dilute with *System suitability solution A* to volume. [NOTE—*System suitability solution B* is stable for up to 6 months if stored in a refrigerator.]

Chromatographic system: Proceed as directed in the Assay, except for the *Detector*.

Detector

UV 365 nm: 3-Hydroxy-5-keto fluvastatin

UV 305 nm: For all other peaks

System suitability

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

Suitability requirements

Resolution: NLT 1.6 between fluvastatin *anti*-isomer and fluvastatin, *System suitability solution B*

Tailing factor: NMT 3.0 for the fluvastatin peak, *System suitability solution B*

Relative standard deviation: NMT 1.0% at 305 nm, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Record the chromatograms at 305 and 365 nm, identify the impurities listed in [Table 2](#), and measure the peak responses.

Calculate the percentage of each impurity, except for 3-hydroxy-5-keto fluvastatin, in the portion of Fluvastatin Sodium taken:

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

r_U = peak response at 305 nm of each impurity from the *Sample solution*

r_S = peak response at 305 nm of fluvastatin from the *Standard solution*

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