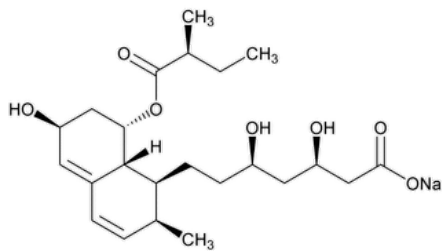


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Pravastatin Sodium



$C_{23}H_{35}NaO_7$ 446.52
1-Naphthaleneheptanoic acid, 1,2,6,7,8,8a-hexahydro- β , δ ,6-trihydroxy-2-methyl-8-(2-methyl-1-oxobutoxy)-, monosodium salt, [1S-[1 α (β S*, δ S*),2 α ,6 α ,8 β (R*),8a α]]-;
Sodium (β R, δ R,1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-hexahydro- β , δ ,6,8-tetrahydroxy-2-methyl-1-naphthaleneheptanoate, 8-[(2S)-2-methylbutyrate] CAS
RN®: 81131-70-6; UNII: 3M8608UQ61.

DEFINITION

Pravastatin Sodium contains NLT 97.5% and NMT 102.0% of pravastatin sodium ($C_{23}H_{35}NaO_7$), calculated on the anhydrous and solvent-free basis.

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy: 197K**
- **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: 0.08 M [phosphoric acid](#) solution. Adjust with a 25% [sodium hydroxide](#) solution to a pH of 5.5.
Solution B: [Acetonitrile](#) and *Solution A* (20:80)
Solution C: [Acetonitrile](#)
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution B (%)	Solution C (%)
0	100	0
7.0	90	10
10.0	62.5	37.5
17.0	62.5	37.5
17.1	100	0
20.0	100	0

System suitability solution: 0.25 mg/mL of [USP Pravastatin 1,1,3,3-Tetramethylbutylamine RS](#) and 0.001 mg/mL of [USP Pravastatin Related Compound A RS](#) in [methanol](#)

Standard solution: 0.25 mg/mL of [USP Pravastatin 1,1,3,3-Tetramethylbutylamine RS](#) in [methanol](#)

Sample solution: 0.2 mg/mL of Pravastatin Sodium in [methanol](#)

Chromatographic system

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

Mode: LC

Detector: UV 238 nm

Column: 4.0-mm × 10-cm; 3-μm packing [L1](#)

Flow rate: 1 mL/min

Injection volume: 10 μL

System suitability

Sample: *System suitability solution*

[NOTE—The relative retention times for pravastatin and pravastatin related compound A are about 1.0 and 1.2, respectively.]

Suitability requirements

Resolution: NLT 1.2 between pravastatin and pravastatin related compound A

Relative standard deviation: NMT 2.0% for the pravastatin peak

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of pravastatin sodium ($C_{23}H_{35}NaO_7$) in the portion of Pravastatin Sodium taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

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

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

C_S = concentration of [USP Pravastatin 1,1,3,3-Tetramethylbutylamine RS](#) in the *Standard solution* (mg/mL)

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

M_{r1} = molecular weight of pravastatin sodium, 446.52

M_{r2} = molecular weight of pravastatin 1,1,3,3-tetramethylbutylamine, 553.78

Acceptance criteria: 97.5%–102.0% on the anhydrous and solvent-free basis

IMPURITIES

• ORGANIC IMPURITIES

[NOTE—The *Standard solution* and the *Sample solution* are maintained at 15° until injected into the chromatograph.]

Diluent: [Methanol](#) and [water](#) (50:50)

Solution A: 0.08 M [phosphoric acid](#) solution. Adjust with [triethylamine](#) to a pH of 7.0.

Solution B: [Acetonitrile](#), *Solution A*, and [water](#) (18:30:52)

Solution C: [Acetonitrile](#), *Solution A*, and [water](#) (60:30:10)

Mobile phase: See [Table 2](#).

Table 2

Time (min)	Solution B (%)	Solution C (%)
0	100	0
3.0	100	0
26.5	0	100
26.6	100	



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