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Fluvastatin Capsules

DEFINITION

Fluvastatin Capsules contain fluvastatin sodium ($C_{24}H_{25}FNNaO_4$) equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of fluvastatin ($C_{24}H_{26}FNO_4$).

IDENTIFICATION

- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
Add the following:
 - ▲ **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay. ▲ (USP 1-Aug-2019)

ASSAY

Change to read:

- **PROCEDURE**
 - ▲ [NOTE—Protect all solutions from light.] ▲ (USP 1-Aug-2019)
 - Buffer:** Prepare a solution containing 40 mL of 25% aqueous [tetramethylammonium hydroxide](#) in 1 L of [water](#). Adjust with approximately 4.5 mL of [phosphoric acid](#) to a pH of 7.2.
 - Solvent mixture:** [Methanol](#) and [acetonitrile](#) (60:40)
 - Solution A:** *Solvent mixture* and *Buffer* (12.5:87.5)
 - Solution B:** *Solvent mixture* and *Buffer* (87.5:12.5)
 - Mobile phase:** See [Table 1](#). ▲ (USP 1-Aug-2019)

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	54	46
6	54	46
17	17	83
20	17	83
20.1	54	46
26.1	54	46

- Diluent:** *Solvent mixture* and *Buffer* (46:54)
- System suitability solution:** 0.42 mg/mL of fluvastatin sodium from [USP Fluvastatin for System Suitability RS](#) in *Diluent*
- Standard solution:** 0.42 mg/mL of [USP Fluvastatin Sodium RS](#), equivalent to 0.4 mg/mL of fluvastatin, in *Diluent*
- Sample stock solution:** Nominally 1.0 mg/mL of fluvastatin from Capsules prepared as follows. Transfer the contents and the empty shells of ▲ a suitable number of ▲ (USP 1-Aug-2019) Capsules, equivalent to 200 mg of fluvastatin, to a 200-mL volumetric flask. Add 100 mL of [methanol](#), and stir with a magnetic or mechanical stirrer for 45 min. Centrifuge a portion of this solution at 4000 rpm for 20 min.
- Sample solution:** Nominally 0.4 mg/mL of fluvastatin from *Sample stock solution* in *Diluent*
- Chromatographic system**
(See [Chromatography \(621\), System Suitability.](#))
- Mode:** LC
- Detector:** UV 305 nm. ▲ For *Identification B*, use a diode array detector in the range of 200–400 nm. ▲ (USP 1-Aug-2019)
- Column:** 4.6-mm × 5-cm; 5-µm packing [L1](#)

Flow rate: 2.0 mL/min**Injection volume:** 25 µL

▲▲ (USP 1-Aug-2019)

System suitability**Samples:** *System suitability solution* ▲ and *Standard solution* ▲ (USP 1-Aug-2019)

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

Suitability requirements**Resolution:** NLT 1.4 between fluvastatin anti-isomer and fluvastatin, *System suitability solution*

▲▲ (USP 1-Aug-2019)

Relative standard deviation: NMT 1.5%, ▲ *Standard solution* ▲ (USP 1-Aug-2019)**Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of the labeled amount of fluvastatin ($C_{24}H_{26}FNO_4$) in the portion of Capsules taken:

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

 r_U = peak response of fluvastatin from the *Sample solution* r_S = peak response of fluvastatin from the *Standard solution* C_S = concentration of [USP Fluvastatin Sodium RS](#) in the *Standard solution* (mg/mL) C_U = nominal concentration of fluvastatin in the *Sample solution* (mg/mL) M_{r1} = molecular weight of fluvastatin, ▲411.47▲ (USP 1-Aug-2019) M_{r2} = molecular weight of fluvastatin sodium, 433.45**Acceptance criteria:** 90.0%–110.0%**PERFORMANCE TESTS****Change to read:**• [DISSOLUTION \(711\)](#).**Medium:** [Water](#); 500 mL**Apparatus 2:** 50 rpm, sinkers not used**Time:** 30 min

▲▲ (USP 1-Aug-2019)

Buffer: 1.534 g of [monobasic ammonium phosphate](#) in 800 mL of [water](#). Adjust with [phosphoric acid](#) or [ammonium hydroxide](#) to a pH of 3.5.**Mobile phase:** [Methanol](#) and *Buffer* (7:3)**Standard solution:**▲ (0.002 × L) mg/mL of [USP Fluvastatin Sodium RS](#) in *Medium*, where L is the label claim in mg/Capsule▲ (USP 1-Aug-2019)[NOTE—A volume of [methanol](#), not exceeding 2% of the final volume of solution, may be used to aid in dissolving [USP Fluvastatin Sodium RS](#).]**Sample solution:** Pass a portion of the solution under test through a suitable filter, discarding the first 2 mL of the filtrate.**Chromatographic system**(See [Chromatography \(621\)](#), *System Suitability*.)**Mode:** LC**Detector:** UV 235 nm**Columns****Guard:** ▲3.2-mm × 1.5-cm;▲ (USP 1-Aug-2019) 7-µm packing [L1](#)**Analytical:** 4.6-mm × 10-cm; 5-µm packing [L1](#)**Flow rate:** 2.0 mL/min**Injection volume:** 50 µL**System suitability****Sample:** *Standard solution***Suitability requirements****Relative standard deviation:** NMT 1.5%**Analysis****Samples:** *Standard solution* and *Sample solution*▲ Calculate the percentage of the labeled amount of fluvastatin ($C_{24}H_{26}FNO_4$) dissolved: