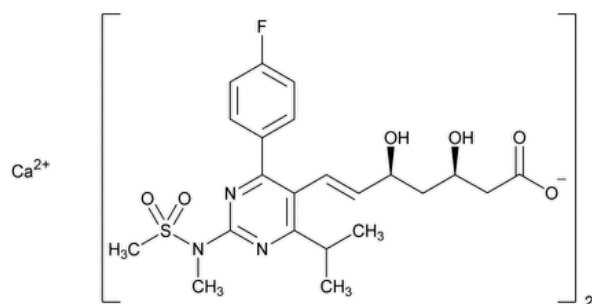


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## Rosuvastatin Calcium

### Change to read:



$\text{Ca}(\text{C}_{22}\text{H}_{27}\text{FN}_3\text{O}_6\text{S})_2$  1001.14

6-Heptenoic acid, 7-[4-(4-fluorophenyl)-6-(1-methylethyl)-2-[methyl(methylsulfonyl)amino]-5-pyrimidinyl]-3,5-dihydroxy-, calcium salt (2:1), (3R,5S,6E);

[S-[R\*,S\*-(E)]]-7-[4-(4-Fluorophenyl)-6-(1-methylethyl)-2-[methyl(methylsulfonyl)amino]-5-pyrimidinyl]-3,5-dihydroxy-6-heptenoic acid, calcium salt (2:1);

Calcium (3R,5S,E)-7-[4-(4-fluorophenyl)-6-isopropyl-2-(N-methylmethylsulfonamido)pyrimidin-5-yl]-3,5-dihydroxyhept-6-enoate salt (1:2) CAS RN®: 147098-20-2; ▲UNII: 83MVU38M7Q.

Rosuvastatin (free acid)

$\text{C}_{22}\text{H}_{28}\text{FN}_3\text{O}_6\text{S}$  481.54 CAS RN®: 287714-41-4; UNII: 413KH5ZJ73.▲ (USP 1-Aug-2024)

### DEFINITION

Rosuvastatin Calcium contains NLT 97.0% and NMT 103.0% of rosuvastatin calcium  $[\text{Ca}(\text{C}_{22}\text{H}_{27}\text{FN}_3\text{O}_6\text{S})_2]$ , calculated on the anhydrous and solvent-free basis.

### IDENTIFICATION

#### Change to read:

- **A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 197A or 197K▲ (USP 1-Aug-2024)

#### Change to read:

- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the ▲Assay.▲ (USP 1-Aug-2024)

- **C.** [IDENTIFICATION TESTS—GENERAL \(191\)](#), [Chemical Identification Tests, Calcium](#)

**Sample solution:** 8 mg/mL of Rosuvastatin Calcium in a mixture of [methanol](#) and [water](#) (50:50)

**Acceptance criteria:** Meets the requirements

### ASSAY

#### Change to read:

#### • PROCEDURE

Protect all solutions containing rosuvastatin calcium and its related compounds from light.

**Solution A:** [Acetonitrile](#), 1% (v/v) aqueous [trifluoroacetic acid](#), and [water](#) (29:1:70)

**Solution B:** [Acetonitrile](#), 1% (v/v) aqueous [trifluoroacetic acid](#), and [water](#) (75:1:24)

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

Table 1

| Time<br>(min) | Solution A<br>(%) | Solution B<br>(%) |
|---------------|-------------------|-------------------|
| 0             | 100               | 0                 |
| 30            | 100               | 0                 |
| 50            | 60                | 40                |
| 60            | 0                 | 100               |
| 70            | 0                 | 100               |
| 71            | 100               | 0                 |
| 80            | 100               | 0                 |

Diluent: [Acetonitrile](#) and [water](#) (25:75)

▲**System suitability stock solution A:** 1 mg/mL of [USP Rosuvastatin System Suitability Mixture RS](#) in *Diluent*▲ (USP 1-Aug-2024)

**System suitability ▲stock**▲ (USP 1-Aug-2024) **solution ▲B:**▲ (USP 1-Aug-2024) 0.25 mg/mL each of [USP Rosuvastatin Related Compound A RS](#) and [USP Rosuvastatin Related Compound B RS](#) in a mixture of [acetonitrile](#) and [water](#) (50:50)

**System suitability ▲stock**▲ (USP 1-Aug-2024) **solution ▲C:**▲ (USP 1-Aug-2024) 0.04 mg/mL of [USP Rosuvastatin Related Compound C RS](#) in a mixture of [acetonitrile](#) and [water](#) (50:50)

▲**System suitability solution:** 0.4 mg/mL of [USP Rosuvastatin System Suitability Mixture RS](#), 5 µg/mL of [USP Rosuvastatin Related Compound A RS](#), 5 µg/mL of [USP Rosuvastatin Related Compound B RS](#), and 0.8 µg/mL of [USP Rosuvastatin Related Compound C RS](#) prepared as follows. Mix 10 mL of System suitability stock solution A, 0.5 mL of System suitability stock solution B, and 0.5 mL of System suitability stock solution C in a 25 mL-volumetric flask. Bring to volume with *Diluent*.▲ (USP 1-Aug-2024)

**Standard solution:** 0.7 mg/mL of [USP Rosuvastatin Calcium RS](#) in *Diluent*

**Sample solution:** 0.7 mg/mL of Rosuvastatin Calcium in *Diluent*

**Chromatographic system**

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

**Mode:** LC

**Detector:** UV 242 nm

**Column:** 3.0-mm × 15-cm; 3-µm packing [L1](#)

**Column temperature:** 40°

**Flow rate:** 0.75 mL/min

**Injection volume:** 10 µL

**System suitability**

**Samples:** *System suitability solution*▲▲ (USP 1-Aug-2024) and *Standard solution*

[NOTE—▲The relative retention times for rosuvastatin related compound B and rosuvastatin related compound C are 2.2 and 2.6, respectively.▲ (USP 1-Aug-2024) See [Table 2](#) for ▲the rest of ▲(USP 1-Aug-2024) the relative retention times.]

**Suitability requirements**

**Resolution:** NLT 2.0 between rosuvastatin and rosuvastatin diastereomer▲▲ (USP 1-Aug-2024) , *System suitability solution* ▲▲ (USP 1-Aug-2024)

**Tailing factor:** NMT 1.5 ▲▲ (USP 1-Aug-2024) , *Standard solution*

▲**Relative standard deviation:** NMT 1.10%, *Standard solution*▲ (USP 1-Aug-2024)

**Analysis**

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of rosuvastatin calcium  $[Ca(C_{22}H_{27}FN_3O_6S)_2]$  in the portion of Rosuvastatin Calcium taken:

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

$r_U$  = peak response of rosuvastatin from the *Sample solution*