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Rosuvastatin Tablets

Change to read:

DEFINITION

Rosuvastatin Tablets contain ▲an amount of rosuvastatin calcium $[\text{Ca}(\text{C}_{22}\text{H}_{27}\text{FN}_3\text{O}_6\text{S})_2]$ equivalent to ▲ (USP 1-Aug-2024) NLT 90% and NMT 110% of the labeled amount of rosuvastatin ($\text{C}_{22}\text{H}_{28}\text{FN}_3\text{O}_6\text{S}$).

IDENTIFICATION

Change to read:

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

Change to read:

• PROCEDURE

Protect all solutions containing rosuvastatin ▲calcium and its related compounds ▲ (USP 1-Aug-2024) from light.

Solution A: 1% [trifluoroacetic acid](#) in [water](#)

Mobile phase: [Acetonitrile](#), *Solution A*, and [water](#) (37:1:62)

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

Standard stock solution: 1 mg/mL of [USP Rosuvastatin Calcium RS](#) prepared as follows. To a suitable amount of [USP Rosuvastatin Calcium RS](#) in a suitable volumetric flask, add [water](#) equal to about 50% of the flask volume. Vigorously mix or sonicate the flask to dissolve the material. Add [acetonitrile](#) equal to about 25% of the total volume and then dilute with [water](#) to volume.

Standard solution: 25 µg/mL of [USP Rosuvastatin Calcium RS](#) from the *Standard stock solution*, in *Diluent*

Sample solution: Nominally 25 µg/mL of rosuvastatin prepared as follows. Transfer a suitable number of Tablets, NLT 5 Tablets for 80-mg Tablet strength and NLT 10 Tablets for all other Tablet strengths, into a suitable extraction flask. Add [water](#) and vigorously mix to disintegrate the Tablets. Add [acetonitrile](#) and mix vigorously. Add more [water](#) to obtain a 25:75 composition of [acetonitrile](#) and [water](#). Pass the solution through a suitable filter. Dilute the filtrate with *Diluent*, if necessary, to the desired concentration.

Chromatographic system

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

Mode: LC

Detector: UV 242 nm. For *Identification A*, use a diode array detector in the range of 200–▲400 ▲ (USP 1-Aug-2024) nm.

Column: 3.2-mm × 25-cm; 5-µm packing [L1](#). [NOTE—A suitable guard column may be used.]

Column temperature: 40°

Flow rate: 0.75 mL/min

Injection volume: 10 µL

Run time: NLT 1.3 times the retention time of rosuvastatin

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.8

Relative standard deviation: NMT ▲1.0% ▲ (USP 1-Aug-2024)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of rosuvastatin ($C_{22}H_{28}FN_3O_6S$) in the portion of Tablets taken:

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

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

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

C_S = concentration of [USP Rosuvastatin Calcium RS](#) in the *Standard solution* (µg/mL)

C_U = nominal concentration of rosuvastatin in the *Sample solution* (µg/mL)

M = number of moles of rosuvastatin per mole of rosuvastatin calcium, 2

M_{r1} = molecular weight of rosuvastatin, 481.54

M_{r2} = molecular weight of rosuvastatin calcium, 1001.14

Acceptance criteria: 90%–110%

PERFORMANCE TESTS

Change to read:

- [DISSOLUTION \(711\)](#).

Protect all solutions containing rosuvastatin ▲calcium and its related compounds ▲ (USP 1-Aug-2024) from light.

Test 1

Medium: Citrate buffer, pH 6.6 (prepare a solution of 14.7 g/L of [sodium citrate dihydrate](#) and 0.33 g/L of [anhydrous citric acid](#); adjust if necessary with ▲[sodium citrate dihydrate](#) ▲ (USP 1-Aug-2024) or [citric acid](#) to a pH of 6.6); 900 mL

Apparatus 2: 50 rpm

Time: 30 min

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

Mobile phase: ▲[Acetonitrile](#) and [water](#) (40:60). To each liter, add 1 mL of [phosphoric acid](#). ▲ (USP 1-Aug-2024)

Standard stock solution: 1 mg/mL of [USP Rosuvastatin Calcium RS](#) in *Diluent*

Standard solution: A solution of concentration similar to the *Sample solution* from the *Standard stock solution*, in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter.

Chromatographic system

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

Mode: LC

Detector: UV 242 nm

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

Flow rate: 1 mL/min

Injection volume: 20 µL

Run time: NLT 2.5 times the retention time of rosuvastatin

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of rosuvastatin ($C_{22}H_{28}FN_3O_6S$) dissolved:

$$\text{Result} = (r_U/r_S) \times C_S \times V \times (1/L) \times [M \times (M_{r1}/M_{r2})] \times 100$$

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

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

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

V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)

M = number of moles of rosuvastatin per mole of rosuvastatin calcium, 2

M_{r1} = molecular weight of rosuvastatin, 481.54

M_{r2} = molecular weight of rosuvastatin calcium, 1001.14

Tolerances: NLT 75% (Q) of the labeled amount of rosuvastatin ($C_{22}H_{28}FN_3O_6S$) is dissolved.

Test 2: If the product complies with this test, the labeling indicates that it meets *Dissolution Test 2*.

Medium: 0.05 M citrate buffer pH 6.6 (to a solution of 10.5 g/L of citric acid monohydrate, add 5.9 g/L of [sodium hydroxide](#) and mix; adjust with 0.2 M [sodium hydroxide](#) or 0.2 M [hydrochloric acid](#) to a pH of 6.6); 900 mL

Apparatus 2: 50 rpm

Time: 30 min

Buffer: Dissolve 2.72 g of [potassium dihydrogen phosphate](#) in 1 L of [water](#) and add 2 mL of [triethylamine](#). Adjust with [phosphoric acid](#) to a pH of 2.5.

Mobile phase: [Acetonitrile](#) and *Buffer* (30:70)

Standard stock solution: 0.5 mg/mL of [USP Rosuvastatin Calcium RS](#) in *Medium*. Sonication may be necessary for complete dissolution.

Standard solution: ($L/900$) mg/mL of [USP Rosuvastatin Calcium RS](#) from the *Standard stock solution*, in *Medium*, Δ where L is the label claim in mg/Tablet Δ (USP 1-Aug-2024)

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45- μ m pore size.

Chromatographic system

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

Mode: LC

Detector: UV 240 nm

Column: 4.6-mm $\times$ 10-cm; 5- μ m packing [L1](#)

Flow rate: 2 mL/min

Injection volume: 20 μ L

Run time: NLT 1.5 times the retention time of rosuvastatin

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of rosuvastatin ($C_{22}H_{28}FN_3O_6S$) dissolved:

$$\text{Result} = (r_U/r_S) \times C_S \times V \times (1/L) \times [M \times (M_{r1}/M_{r2})] \times 100$$

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

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

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

V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)

M = number of moles of rosuvastatin per mole of rosuvastatin calcium, 2

M_{r1} = molecular weight of rosuvastatin, 481.54

M_{r2} = molecular weight of rosuvastatin calcium, 1001.14

Tolerances: NLT 80% (Q) of the labeled amount of rosuvastatin ($C_{22}H_{28}FN_3O_6S$) is dissolved.

Test 3: If the product complies with this test, the labeling indicates that it meets *Dissolution Test 3*.