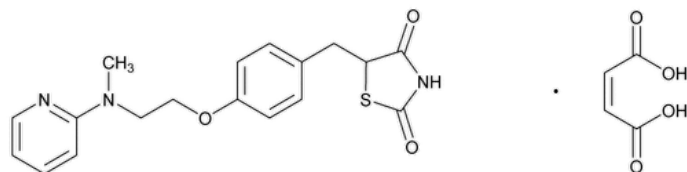


Status: Currently Official on 16-Feb-2025
 Official Date: Official as of 01-May-2020
 Document Type: USP Monographs
 DocId: GUID-2FB091AC-3D96-4D10-8D47-762EE6F51DFC_4_en-US
 DOI: https://doi.org/10.31003/USPNF_M73980_04_01
 DOI Ref: b8jp5

© 2025 USPC
 Do not distribute

Rosiglitazone Maleate



$C_{18}H_{19}N_3O_3S \cdot C_4H_4O_4$ 473.50

(±)-5-[p-[2-(Methyl-2-pyridylamino)ethoxy]benzyl]-2,4-thiazolidinedione maleate (1:1);

(RS)-5-[[4-[(2-[Methyl(2-pyridinyl)amino]ethyl)oxy] phenyl]methyl]-1,3-thiazolidine-2,4-dione (Z)-2-butenedioate CAS RN®: 155141-29-0; UNII: KX2339DP44.

DEFINITION

Rosiglitazone Maleate contains NLT 98.0% and NMT 102.0% of $C_{18}H_{19}N_3O_3S \cdot C_4H_4O_4$, calculated on the anhydrous and solvent-free basis.

IDENTIFICATION

Change to read:

- A. ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197M](#) ▲ (CN 1-MAY-2020)
- 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

PROCEDURE

Buffer: Dissolve 5.75 g of phosphoric acid in 800 mL water, adjust with 4 N sodium hydroxide to a pH of 3.0, and dilute with water to 1 L.

Mobile phase: Acetonitrile and *Buffer* (25:75)

System suitability solution: Transfer 2.5 mg of [USP Rosiglitazone Maleate RS](#) and 1 mg of [USP Rosiglitazone Related Compound A RS](#) to a 50-mL volumetric flask, dissolve in 1 mL of stabilizer-free tetrahydrofuran, and dilute with *Mobile phase* to volume.

Standard solution: 0.05 mg/mL of [USP Rosiglitazone Maleate RS](#) in *Mobile phase*

Sample solution: 0.05 mg/mL of Rosiglitazone Maleate in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 235 nm

Column: 4.6-mm × 25-cm; 5-μm packing L1

Column temperature: 40°

Flow rate: 1 mL/min

Injection size: 20 μL

System suitability

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

Suitability requirements

Resolution: Greater than 2.0 between rosiglitazone and rosiglitazone related compound A, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 1.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of rosiglitazone maleate ($C_{18}H_{19}N_3O_3S \cdot C_4H_4O_4$) in the portion of Rosiglitazone Maleate 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 Rosiglitazone Maleate RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Rosiglitazone Maleate in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the anhydrous and solvent-free basis

OTHER COMPONENTS

• CONTENT OF MALEIC ACID

Buffer: Prepare 0.1 M sodium phosphate buffer as follows. Add 11.5 g of phosphoric acid to 800 mL of water, adjust with 2 N sodium hydroxide to a pH of 3.0, and dilute with water to 1 L.

Mobile phase: Methanol and *Buffer* (50:50)

Diluent: Methanol and water (50:50)

System suitability solution: 0.1 µg/mL of [USP Fumaric Acid RS](#) and 0.04 mg/mL of [USP Rosiglitazone Maleate RS](#) in *Diluent*

Standard solution: 0.01 mg/mL of [USP Maleic Acid RS](#) in *Diluent*

Sample solution: 0.04 mg/mL of Rosiglitazone Maleate in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 212 nm

Column: 4.6-mm × 15-cm; 5-µm packing L14

Column temperature: 40°

Flow rate: 1.5 mL/min

Injection size: 20 µL

System suitability

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

[NOTE—The relative retention times for rosiglitazone, maleic acid, and fumaric acid are 0.5, 1.0, and 1.8, respectively.]

Suitability requirements

Resolution: NLT 2.0 between maleic acid and fumaric acid, *System suitability solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of maleic acid in the portion of Rosiglitazone Maleate taken:

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

r_U = peak response of maleic acid from the *Sample solution*

r_S = peak response of maleic acid from the *Standard solution*

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

C_U = concentration of Rosiglitazone Maleate in the *Sample solution* (mg/mL)

Acceptance criteria: 23.5%–26.0%

IMPURITIES

• [RESIDUE ON IGNITION, \(281\)](#): NMT 0.2%, using an ignition temperature of 800 ± 25°

• ORGANIC IMPURITIES

[NOTE—Protect the *System suitability solution* and *Sample solution* from light.]

Buffer 1: Prepare 0.05 M dibasic potassium phosphate buffer as follows. Dissolve 11.4 g of dibasic potassium phosphate trihydrate in 800 mL of water, adjust with a mixture of phosphoric acid and water (1:1) to a pH of 7.0, and dilute with water to 1 L.

Solution A: Acetonitrile and *Buffer 1* (30:70)

Solution B: Acetonitrile and *Buffer 1* (70:30)