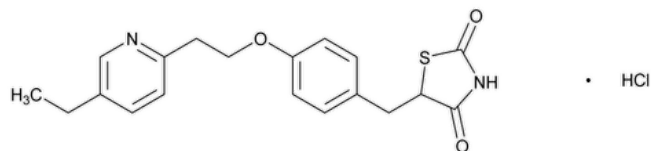


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Pioglitazone Hydrochloride



$C_{19}H_{20}N_2O_3S \cdot HCl$ 392.90

2,4-Thiazolidinedione, 5-[[4-[2-(5-ethyl-2-pyridinyl)ethoxy]phenyl]methyl]-, monohydrochloride, ($\pm$);

($\pm$)-5-[p-[2-(5-Ethyl-2-pyridyl)ethoxy]benzyl]-2,4-thiazolidinedione monohydrochloride CAS RN[®]: 112529-15-4; UNII: JQT35NPK6C.

DEFINITION

Pioglitazone Hydrochloride contains NLT 98.0% and NMT 102.0% of $C_{19}H_{20}N_2O_3S \cdot HCl$, calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K ▲](#) (CN 1-MAY-2020)
- **B.** [IDENTIFICATION TESTS—GENERAL, Chloride\(191\)](#): Dissolve 25 mg of Pioglitazone Hydrochloride in 0.5 mL of nitric acid, and add 2 mL of dilute nitric acid. It meets the requirements of the test for *Chloride*.
- **C.** The retention time of the pioglitazone peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

PROCEDURE

Mobile phase: Acetonitrile, 0.1 M ammonium acetate, and glacial acetic acid (25:25:1)

Standard solution: Prepare a 0.5 mg/mL solution of [USP Pioglitazone Hydrochloride RS](#) in methanol, and dilute with *Mobile phase* to obtain a solution containing 50 µg/mL of pioglitazone hydrochloride.

System suitability stock solution: 0.5 mg/mL of [USP Pioglitazone Hydrochloride RS](#) and 0.13 mg/mL of benzophenone in methanol

System suitability solution: Dilute *System suitability stock solution* with *Mobile phase* to obtain a solution containing 50 µg/mL of pioglitazone hydrochloride and 13 µg/mL of benzophenone.

Sample solution: Prepare a 0.5 mg/mL solution of pioglitazone hydrochloride in methanol, and dilute with *Mobile phase* to obtain a solution containing 50 µg/mL of pioglitazone hydrochloride.

Chromatographic system

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

Mode: LC

Detector: UV 269 nm

Column: 4.6-mm × 15-cm; 5-µm packing L1

Column temperature: 25 ± 2.5°

Flow rate: 0.7 mL/min

[NOTE—Adjust the flow rate so that the retention time of the pioglitazone peak is about 7 min.]

Injection size: 20 µL

System suitability

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

[NOTE—The approximate relative retention times for pioglitazone and benzophenone are 1.0 and 2.6, respectively.]

Suitability requirements

Tailing factor: NMT 1.5 for pioglitazone and benzophenone, *System suitability solution*

Resolution: NLT 15 between pioglitazone and benzophenone, *System suitability solution*

Relative standard deviation: NMT 2.0% for six replicate injections, *Standard solution*

Analysis**Samples:** *Standard solution* and *Sample solution*Calculate the percentage of $C_{19}H_{20}N_2O_3S \cdot HCl$ in the portion of Pioglitazone Hydrochloride 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 Pioglitazone Hydrochloride RS](#) in the *Standard solution* (µg/mL) C_U = concentration of Pioglitazone Hydrochloride in the *Sample solution* (µg/mL)**Acceptance criteria:** 98.0%–102.0% on the anhydrous basis**IMPURITIES****INORGANIC IMPURITIES**

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

ORGANIC IMPURITIES• **PROCEDURE****Mobile phase and System suitability stock solution:** Proceed as directed in the Assay.**System suitability solution:** Dilute the *System suitability stock solution* with *Mobile phase* to obtain a solution containing 25 µg/mL of pioglitazone hydrochloride and 6.5 µg/mL of benzophenone.**Sample solution:** 0.2 mg/mL of pioglitazone hydrochloride dissolved in 20% of the final volume with methanol, then diluted with *Mobile phase* to final volume**Standard solution:** 1 µg/mL of pioglitazone hydrochloride prepared by diluting the *Sample solution* with *Mobile phase***Chromatographic system**(See [Chromatography \(621\)](#), [System Suitability](#).)**Mode:** LC**Detector:** UV 269 nm**Column:** 4.6-mm × 15-cm; 5-µm packing L1**Column temperature:** 25 ± 2.5°**Flow rate:** 0.7 mL/min

[NOTE—Adjust the flow rate so that the retention time of the pioglitazone peak is about 7 min.]

Injection size: 40 µL**Run time:** At least four times the retention time of pioglitazone**System suitability****Samples:** *System suitability solution* and *Standard solution***Suitability requirements****Tailing factor:** NMT 1.5 for pioglitazone and benzophenone, *System suitability solution***Resolution:** NLT 15 between pioglitazone and benzophenone, *System suitability solution***Relative standard deviation:** NMT 3.0%, *Standard solution***Analysis****Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Pioglitazone Hydrochloride taken:

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

 r_U = peak response of each individual impurity from the *Sample solution* r_S = peak response of pioglitazone from the *Standard solution* D = dilution factor used to prepare the *Standard solution*, 0.005**Acceptance criteria****Individual impurities:** See [Impurity Table 1](#).