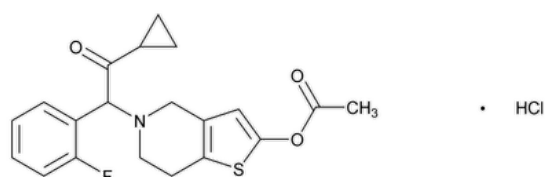


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Prasugrel Hydrochloride

Change to read:



$C_{20}H_{20}FNO_3 \cdot HCl$ 409.90

Ethanone, 2-[2-(acetyloxy)-6,7-dihydrothieno[3,2-c]pyridin-5(4H)-yl]-1-cyclopropyl-2-(2-fluorophenyl)-, hydrochloride;

5-[2-Cyclopropyl-1-(2-fluorophenyl)-2-oxoethyl]-4,5,6,7-tetrahydrothieno[3,2-c]pyridin-2-yl acetate hydrochloride CAS RN[®]: 389574-19-0;

▲UNII: ▲G89JQ59I13.

Prasugrel (free base)

$C_{20}H_{20}FNO_3$ 373.44 CAS RN[®]: 150322-43-3; UNII: 34K66TBT99.▲ (USP 1-Aug-2023)

DEFINITION

Prasugrel Hydrochloride contains NLT 97.0% and NMT 102.0% of prasugrel hydrochloride ($C_{20}H_{20}FNO_3 \cdot HCl$), calculated on the anhydrous and solvent-free basis.

IDENTIFICATION

• **A. [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#):** 197K or 197A

Change to read:

• **B.** The retention time of the ▲major▲ (USP 1-Aug-2023) peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

• **C. [IDENTIFICATION TESTS—GENERAL \(191\)](#), [Chemical Identification Tests, Chloride](#):** Meets the requirements

ASSAY

Change to read:

• PROCEDURE

Buffer: 10 mM [monobasic potassium phosphate](#) in [water](#). Adjust with [phosphoric acid](#) to a pH of 2.8.

Mobile phase: [Acetonitrile](#) and *Buffer* (35:65)

Diluent: [Acetonitrile](#) and [water](#) (70:30)

Standard solution: 0.1 mg/mL of [USP Prasugrel Hydrochloride RS](#) in *Diluent*

Sample solution: 0.1 mg/mL of Prasugrel Hydrochloride in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 260 nm

Column: 4.6-mm × 15-cm; 5-μm packing [L1](#)

Column temperature: 40°

Flow rate: 1 mL/min

Injection volume: 10 μL

Run time: NLT 2.5 times the retention time of prasugrel

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0▲ (USP 1-Aug-2023)

Relative standard deviation: NMT ▲0.73%▲ (USP 1-Aug-2023)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of prasugrel hydrochloride ($C_{20}H_{20}FNO_3S \cdot HCl$) in the portion of Prasugrel Hydrochloride taken:

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

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

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

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

C_U = concentration of Prasugrel Hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 97.0%–102.0% on the anhydrous and solvent-free basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.2%

Delete the following:

▲• **ORGANIC IMPURITIES, PROCEDURE 1**▲ (USP 1-Aug-2023)

Delete the following:

▲• **ORGANIC IMPURITIES, PROCEDURE 2**▲ (USP 1-Aug-2023)

Add the following:

▲• **ORGANIC IMPURITIES**

Buffer: 3 mL of [phosphoric acid](#) in 1000 mL of [water](#). Adjust with 10% (w/v) [potassium hydroxide](#) solution to a pH of 2.9.

Solution A: *Buffer*

Solution B: [Acetonitrile](#) and [water](#) (90:10)

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

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	68	32
18	68	32
38	42	58
50	42	58
50.5	68	32
60	68	32

System suitability solution: 1.5 mg/mL of [USP Prasugrel Hydrochloride RS](#) and 7.5 µg/mL of [USP Prasugrel Related Compound D RS](#) in *Solution B*

Standard solution: 1.5 µg/mL of [USP Prasugrel Hydrochloride RS](#) in *Solution B*

Sensitivity solution: 0.75 µg/mL of [USP Prasugrel Hydrochloride RS](#) from the *Standard solution* in *Solution B*

Sample solution: 1.5 mg/mL of Prasugrel Hydrochloride in *Solution B*

Chromatographic system

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

Mode: LC

Detector: UV 235 nm