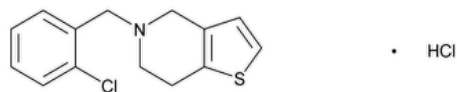


Status: Currently Official on 17-Feb-2025
 Official Date: Official as of 01-May-2020
 Document Type: USP Monographs
 DocId: GUID-2DF352A9-8F4D-40F2-B0A9-E3C0EFC66522_4_en-US
 DOI: https://doi.org/10.31003/USPNF_M83560_04_01
 DOI Ref: 202zz

© 2025 USPC
 Do not distribute

Ticlopidine Hydrochloride



$C_{14}H_{14}ClNS \cdot HCl$ 300.25

Thieno[3,2-c]pyridine, 5-[(2-chlorophenyl)methyl]-4,5,6,7-tetrahydro-, hydrochloride;

5-(o-Chlorobenzyl)-4,5,6,7-tetrahydrothieno-[3,2-c]pyridine hydrochloride CAS RN®: 53885-35-1; UNII: A1L4914FMF.

DEFINITION

Ticlopidine Hydrochloride contains NLT 98.0% and NMT 102.0% of $C_{14}H_{14}ClNS \cdot HCl$, calculated on the dried 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.
- **C.** [IDENTIFICATION TESTS—GENERAL, Chloride\(191\)](#): Meets the requirements

ASSAY

PROCEDURE

Buffer: 1.1 g of monobasic sodium phosphate and 0.28 g of dibasic sodium phosphate in 1000 mL of water. The pH of solution is between 6.1 and 6.6. If necessary, adjust to the required pH using phosphoric acid or sodium hydroxide.

Mobile phase: Acetonitrile, methanol, and *Buffer* (6:7:7)

System suitability solution: 0.2 mg/mL of [USP Ticlopidine Hydrochloride RS](#) and 0.2 mg/mL of [USP Sulconazole Nitrate RS](#) in *Mobile phase*.

[NOTE—Sonication may be necessary for complete dissolution.]

Standard solution: 0.4 mg/mL of [USP Ticlopidine Hydrochloride RS](#) in *Mobile phase*

Sample solution: 0.4 mg/mL of Ticlopidine Hydrochloride in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 215 nm

Column: 4.6-mm × 25-cm; 10-μm packing L7

Flow rate: 2 mL/min

Column temperature: 40°

Run time: 1.5 times the retention time of the ticlopidine peak

Injection size: 10 μL

System suitability

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

Suitability requirements

Resolution: NLT 2.6 between ticlopidine hydrochloride and sulcanazole nitrate, *System suitability solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of $C_{14}H_{14}ClNS \cdot HCl$ in the portion of Ticlopidine Hydrochloride taken:

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

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

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

C_S = concentration of ticlopidine in the *Standard solution*

C_U = concentration of ticlopidine in the *Sample solution*

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

INORGANIC IMPURITIES

- **RESIDUE ON IGNITION (281):** NMT 0.1% on a 1-g sample

ORGANIC IMPURITIES

• PROCEDURE 1

Adsorbent: 0.25-mm thickness of silica

Developing solvent: Butanol, water, and glacial acetic acid (4:5:1). Shake well in a separatory funnel, allow it to settle, discard the lower aqueous layer, and use the upper organic layer.

Diluent: Methylene chloride and methanol (1:2)

Iodine–methanol reagent: Iodine TS and methanol (1:1)

Standard solution A: 15 mg/mL of [USP Ticlopidine Hydrochloride RS](#) in *Diluent*

Standard solution B: 2.5 mg/mL of each of [USP Ticlopidine Related Compound A RS](#) and [USP Ticlopidine Related Compound B RS](#) in *Diluent*

Sample solution: 15 mg/mL of Ticlopidine Hydrochloride in *Diluent*

Combined standard solution: Transfer 1.5 mL of *Standard solution B* and 250 µL of the *Sample solution* to a 25-mL volumetric flask and dilute to volume with *Diluent*.

Application size: 2, 5, and 10 µL of the *Combined standard solution* and 20 µL of the *Sample solution*

Analysis

Samples: *Sample solution* and *Combined standard solution*

Develop the plate to a distance of at least 15 cm from the origin, and remove the plate and air dry for at least 1 h. Analyze visually under UV light. Estimate the amounts of ticlopidine related compound A and ticlopidine related compound B. Spray the plate with the *Iodine–methanol reagent*, and estimate any other impurities by comparing to the ticlopidine hydrochloride spots in the *Combined standard solution*.

Acceptance criteria

Individual impurities: See [Impurity Table 1](#).

Impurity Table 1

Name	Retardation Factor (R_f)	Acceptance Criteria, NMT (%)
Ticlopidine hydrochloride	1.00	—
Ticlopidine hydrochloride related compound A ^a	1.26	0.5
Ticlopidine hydrochloride related compound B ^b	1.41	0.5

^a (4-Oxo-4,5,6,7-tetrahydrothieno-[3,2-c]pyridine).

^b (5-(2-Chlorobenzyl)-4-oxo-4,5,6,7-tetrahydrothieno-[3,2-c]pyridine).

• PROCEDURE 2

Buffer, Mobile phase, System suitability solution, Standard solution, Sample solution, and Chromatographic system: Proceed as directed in the Assay.

Analysis

Samples: *Standard solution* and *Sample solution*