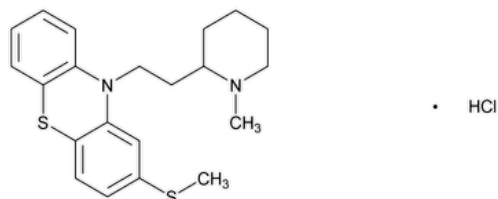


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Thioridazine Hydrochloride



$C_{21}H_{26}N_2S_2 \cdot HCl$ 407.04

10*H*-Phenothiazine, 10-[2-(1-methyl-2-piperidinyl) ethyl]-2-(methylthio)-, monohydrochloride;

10-[2-(1-Methyl-2-piperidyl)ethyl]-2-(methylthio) phenothiazine monohydrochloride CAS RN[®]: 130-61-0; UNII: 4WCI67NK8M.

DEFINITION

Thioridazine Hydrochloride contains NLT 99.0% and NMT 101.0% of thioridazine hydrochloride ($C_{21}H_{26}N_2S_2 \cdot HCl$), calculated on the dried basis.

[NOTE—Throughout the following procedures, protect test or Assay samples, the Reference Standard, and solutions containing them, by conducting the analyses without delay, under subdued light, or by using low-actinic glassware.]

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197K
- **B. IDENTIFICATION TESTS—GENERAL (191), Chemical Identification Tests, Chloride**

Sample solution: 10 mg/mL in a mixture of [water](#) and [alcohol](#) (50:50)

Acceptance criteria: Meets the requirements of the test for amine hydrochlorides

ASSAY

• PROCEDURE

Solution A: [Glacial acetic acid](#) and [acetic anhydride](#) (50:50)

Sample solution: Dissolve 350 mg of Thioridazine Hydrochloride in 80 mL of *Solution A*.

Titrimetric system

(See [Titrimetry \(541\)](#).)

Mode: Direct titration

Titrant: [0.1 N perchloric acid VS](#)

Blank: *Solution A*

Endpoint detection: Potentiometric

Analysis

Samples: *Sample solution* and *Blank*

Titrate the *Sample solution* with *Titrant*. Perform a blank determination, and make any necessary correction.

Calculate the percentage of thioridazine hydrochloride ($C_{21}H_{26}N_2S_2 \cdot HCl$) in the portion of Thioridazine Hydrochloride taken:

$$\text{Result} = \{[(V_S - V_B) \times N_A \times F]/W\} \times 100$$

V_S = *Titrant volume consumed by the Sample solution* (mL)

V_B = *Titrant volume consumed by the Blank* (mL)

N_A = *normality of the Titrant* (mEq/mL)

F = *equivalency factor*, 407.04 (mg/mEq)

W = *sample weight* (mg)

Acceptance criteria: 99.0%–101.0% on the dried basis

IMPURITIES

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

Change to read:

- ▲ [SELENIUM \(291\)](#), [Procedures, Procedure 1](#) ▲ (CN 1-JUN-2023)

Sample: 100 mg of sample mixed with 100 mg of magnesium oxide

Acceptance criteria: NMT 30 ppm

ORGANIC IMPURITIES

Diluent: [Methanol](#) and [ammonium hydroxide](#) (98:2)

Standard solution: 20.0 mg/mL of [USP Thioridazine Hydrochloride RS](#) in *Diluent*

Comparison solution A: 0.01 mg/mL from *Standard solution* in *Diluent* (0.05%)

Comparison solution B: 0.02 mg/mL from *Standard solution* in *Diluent* (0.1%)

Comparison solution C: 0.025 mg/mL from *Standard solution* in *Diluent* (0.125%)

Comparison solution D: 0.067 mg/mL from *Standard solution* in *Diluent* (0.33%)

Comparison solution E: 0.1 mg/mL from *Standard solution* in *Diluent* (0.5%)

Sample solution: 20 mg/mL of Thioridazine Hydrochloride in *Diluent*

Chromatographic system

(See [Chromatography \(621\)](#), [General Procedures, Thin-Layer Chromatography](#).)

Mode: TLC

Application volume: 5 µL

Developing solvent system: [Chloroform](#), [isopropyl alcohol](#), and [ammonium hydroxide](#) (74:25:1)

Spray reagent: [Dragendorff's TS](#) and [hydrogen peroxide TS](#)

Analysis

Samples: *Standard solution*, *Comparison solutions A–E*, and *Sample solution*

Proceed as directed in [Ordinary Impurities \(466\)](#). Examine the plate under short- and long-wavelength UV light, then spray the plate with [Dragendorff's TS](#), dry the plate with a stream of nitrogen, and spray with [hydrogen peroxide TS](#).

Acceptance criteria: Any secondary spot from the *Sample solution* is NMT 0.5%, and the sum of all secondary spots is NMT 0.5%.

SPECIFIC TESTS

- [MELTING RANGE OR TEMPERATURE \(741\)](#): 159°–165°; the range between beginning and end of melting does not exceed 3°

- [pH \(791\)](#)

Sample solution: 10 mg/mL

Acceptance criteria: 4.2–5.2

- [LOSS ON DRYING \(731\)](#)

Analysis: Dry at 105° for 4 h.

Acceptance criteria: NMT 0.4%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.

- [USP REFERENCE STANDARDS \(11\)](#)

[USP Thioridazine Hydrochloride RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
THIORIDAZINE HYDROCHLORIDE	Documentary Standards Support	SM42020 Small Molecules 4
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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