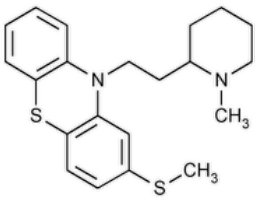
Status: Currently Official on 17-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-066E87FB-7DCE-488D-ACA3-AE4FD000AA2D_4_en-US
DOI: https://doi.org/10.31003/USPNF_M82930_04_01
DOI Ref: 56va8

Thioridazine



$C_{21}H_{26}N_2S_2$ 370.57

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

10-[2-(1-Methyl-2-piperidyl)ethyl]-2-(methylthio) phenothiazine CAS RN®: 50-52-2; UNII: N3D6TG58NI.

DEFINITION

Thioridazine contains NLT 99.0% and NMT 101.0% of $C_{21}H_{26}N_2S_2$, calculated on the dried basis.

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

IDENTIFICATION

Change to read:

• **A.** ▲Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: **197K**▲ (CN 1-May-2020)

ASSAY

• **Procedure**

Sample solution: 300 mg of Thioridazine in 60 mL of glacial acetic acid

Analysis: Titrate with 0.1 N perchloric acid VS, determining the endpoint potentiometrically. Perform a blank determination, and make any necessary correction (see *Titrimetry* ⟨541⟩). Each mL of 0.1 N perchloric acid is equivalent to 37.06 mg of $C_{21}H_{26}N_2S_2$.

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

IMPURITIES

• **Residue on Ignition** ⟨281⟩**:** NMT 0.1%

• **Organic Impurities**

[NOTE—Conduct this procedure without delay, under subdued light.]

Diluent: Methanol and ammonium hydroxide (49:1)

Standard solution A: 50 µg/mL of USP Thioridazine RS in *Diluent*

Standard solution B: 20 µg/mL of USP Thioridazine RS in *Diluent*

Sample solution: 10 mg/mL of Thioridazine in *Diluent*

Chromatographic system

(See *Chromatography* ⟨621⟩, *Thin-Layer Chromatography*.)

Mode: TLC

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture

Application volume: 5 µL

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

Analysis

Samples: *Standard solution A*, *Standard solution B*, and *Sample solution*

Immediately develop until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the chamber, mark the solvent front, allow the solvent to evaporate, and examine the plate under short-wavelength UV light.

Acceptance criteria: The chromatograms show principal spots at about the same R_F value; no secondary spot, if present from the *Sample solution*, is more intense than the principal spot from *Standard solution A* (0.5%); and the sum of the intensities of all secondary spots, if present in the *Sample solution*, is NMT 0.5%.

SPECIFIC TESTS

• **Loss on Drying ⟨731⟩:** Dry a sample in vacuum at 50° for 4 h: it loses NMT 0.5% of its weight.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed, light-resistant containers.

• **USP Reference Standards ⟨11⟩**

USP Thioridazine RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
THIORIDAZINE	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:
Pharmacopeial Forum: Volume No. PF 44(6)

Current DocID: GUID-066E87FB-7DCE-488D-ACA3-AE4FD000AA2D_4_en-US

DOI: https://doi.org/10.31003/USPNF_M82930_04_01

DOI ref: 56va8