Status: Currently Official on 17-Feb-2025
Official Date: Official as of 01-Aug-2013
Document Type: USP Monographs
DocId: GUID-501F73EF-1710-49AC-B258-2C3640990142_1_en-US
DOI: https://doi.org/10.31003/USPNF_M83030_01_01
DOI Ref: a6q2e

Thioridazine Hydrochloride Tablets

DEFINITION

Thioridazine Hydrochloride Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of thioridazine hydrochloride ($C_{21}H_{26}N_2S_2 \cdot HCl$).

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

IDENTIFICATION

• **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Mobile phase: Acetonitrile, water, and triethylamine (850:150:1)

System suitability solution: 0.1 mg/mL of USP Mesoridazine Besylate RS and 0.11 mg/mL of USP Thioridazine Hydrochloride RS in methanol

Standard solution: 125 µg/mL of USP Thioridazine Hydrochloride RS in methanol. Sonication may be used to aid dissolution.

Sample stock solution: Nominally 1.0 mg/mL prepared as follows. Weigh and finely powder NLT 20 Tablets. Transfer a weighed portion of the powder, equivalent to 100 mg of thioridazine hydrochloride, to a 100-mL volumetric flask. Add 80 mL of methanol, and shake by mechanical means for 30 min. Dilute with methanol to volume, and sonicate for 45 min with intermittent shaking. Allow the undissolved solids to settle, and filter, discarding the first 20 mL of the filtrate.

Sample solution: 125 µg/mL in methanol from a portion of filtrate from the *Sample stock solution*. Pass through a suitable filter of 0.45-µm pore size.

Chromatographic system

(See *Chromatography (621), System Suitability*.)

Mode: LC

Detector: UV 265 nm

Column: 4.6-mm × 25-cm; packing L1

Flow rate: 2.5 mL/min

Injection volume: 10 µL

System suitability

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

[Note—The relative retention times for mesoridazine and thioridazine are 0.44 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.0 between mesoridazine and thioridazine, *System suitability solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

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

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

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

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

C_S = concentration of USP Thioridazine Hydrochloride RS in the *Standard solution* (µg/mL)

C_U = nominal concentration of thioridazine hydrochloride in the *Sample solution* (µg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution** ⟨711⟩

Medium: 0.01 N hydrochloric acid; 1000 mL

Apparatus 2: 75 rpm

Time: 60 min

Sample solution: Pass a portion of the solution under test through a suitable filter. Dilute with *Medium*, if necessary, to a concentration similar to that of the *Standard solution*.

Standard solution: USP Thioridazine Hydrochloride RS in *Medium* at a known concentration

Instrumental conditions

(See *Ultraviolet-Visible Spectroscopy* ⟨857⟩.)

Mode: UV

Analytical wavelength: 262 nm

Blank: *Medium*

Tolerances: NLT 75% (*Q*) of the labeled amount of thioridazine hydrochloride ($C_{21}H_{26}N_2S_2 \cdot HCl$) is dissolved.

• **Uniformity of Dosage Units** ⟨905⟩**:** Meet the requirements

ADDITIONAL REQUIREMENTS

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

• **USP Reference Standards** ⟨11⟩

USP Mesoridazine Besylate RS

USP Thioridazine Hydrochloride RS

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

Topic/Question	Contact	Expert Committee
THIORIDAZINE HYDROCHLORIDE TABLETS	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 38(3)

Current DocID: GUID-501F73EF-1710-49AC-B258-2C3640990142_1_en-US

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