Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-6938C7B9-FEB0-4E1A-B3C0-191DD4F05D4C_2_en-US
DOI: https://doi.org/10.31003/USPNF_M71230_02_01
DOI Ref: xi6md

Propylthiouracil Tablets

DEFINITION
Propylthiouracil Tablets contain NLT 93.0% and NMT 107.0% of the labeled amount of propylthiouracil ($C_7H_{10}N_2OS$).

IDENTIFICATION

Change to read:

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

Sample: Boil a quantity of finely powdered Tablets equivalent to 100 mg of propylthiouracil with 10 mL of alcohol under a reflux condenser for 20 min. Filter while hot, and evaporate the filtrate on a steam bath to dryness. Use the residue.

Acceptance criteria: Meet the requirements

• **B.** 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**

Buffer: Transfer 3.40 g of monobasic potassium phosphate to a 1000-mL beaker. Add 500 mL of water, and stir until dissolved. Adjust with phosphoric acid or 0.1 N sodium hydroxide to a pH of 4.6, and add 500 mL of water. Adjust the resulting solution with phosphoric acid or 0.1 N sodium hydroxide to a pH of 4.6.

Mobile phase: Acetonitrile and *Buffer* (20:80)

Standard stock solution: 0.5 mg/mL of USP Propylthiouracil RS prepared as follows. Transfer 25 mg of USP Propylthiouracil RS to a 50-mL volumetric flask, add 5 mL of methanol, and sonicate for 5 min. Add 25 mL of water, and shake by mechanical means for 15 min. Dilute with water to volume.

Standard solution: 50 µg/mL of USP Propylthiouracil RS from the *Standard stock solution* in water

Sample stock solution: Nominally 0.5 mg/mL of propylthiouracil from Tablets prepared as follows. Finely powder NLT 20 Tablets. Transfer a portion of the powder, equivalent to 50 mg of propylthiouracil to a 100-mL volumetric flask, add 10 mL of methanol, and sonicate for 5 min. Add 50 mL of water, and shake by mechanical means for 20 min. Dilute with water to volume and pass through a suitable filter. Use the filtrate.

Sample solution: Nominally 50.0 µg/mL of propylthiouracil from the *Sample stock solution* in water

Chromatographic system

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

Mode: LC

Detector: UV 272 nm

Column: 4.6-mm × 10-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 3500 theoretical plates

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of propylthiouracil ($C_7H_{10}N_2OS$) in the portion of Tablets taken:

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

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

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

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

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

Acceptance criteria: 93.0%–107.0%

PERFORMANCE TESTS

• **Dissolution** ⟨711⟩

Medium: Water; 900 mL

Apparatus 1: 100 rpm

Time: 30 min

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

Sample solution: Pass a portion of the solution under test through a suitable filter and dilute with *Medium* to a concentration that is similar to the *Standard solution*.

Instrumental conditions

Mode: UV

Analytical wavelength: Maximum absorbance at about 274 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Determine the amount of propylthiouracil ($C_7H_{10}N_2OS$) dissolved from the UV absorbances.

Tolerances: NLT 85% (*Q*) of the labeled amount of propylthiouracil ($C_7H_{10}N_2OS$) is dissolved.

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

ADDITIONAL REQUIREMENTS

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

• **USP Reference Standards** ⟨11⟩

USP Propylthiouracil RS

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

Topic/Question	Contact	Expert Committee
PROPYLTHIOURACIL TABLETS	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: GUID-6938C7B9-FEB0-4E1A-B3C0-191DD4F05D4C_2_en-US

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