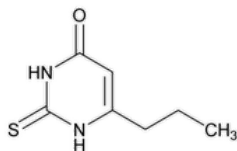


Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2022
Document Type: USP Monographs
DocId: GUID-7E8B98DD-A362-44A5-972C-9FFA7B645C5A_5_en-US
DOI: https://doi.org/10.31003/USPNF_M71200_05_01
DOI Ref: h1fb1

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Propylthiouracil



$C_7H_{10}N_2OS$ 170.23

4(1*H*)-Pyrimidinone, 2,3-dihydro-6-propyl-2-thioxo-;

6-Propyl-2-thiouracil CAS RN®: 51-52-5; UNII: 721M9407IY.

DEFINITION

Propylthiouracil contains NLT 98.0% and NMT 100.5% of propylthiouracil ($C_7H_{10}N_2OS$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A. [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#):** ▲197A or ▲ (USP 1-May-2022) 197K

ASSAY

• PROCEDURE

Sample: 300 mg

Analysis: Transfer the *Sample* to a 500-mL conical flask, and add 30 mL of water. Add from a buret 30 mL of 0.1 N sodium hydroxide VS, heat to boiling, and agitate until the solution is complete. Wash down any particles on the wall of the flask with a few milliliters of water, add 50 mL of 0.1 N silver nitrate while mixing, and boil gently for 7 min. Cool to room temperature and continue to titrate with 0.1 N sodium hydroxide VS, determining the endpoint potentiometrically using a glass-calomel electrode system. Each milliliter of 0.1 N sodium hydroxide is equivalent to 8.512 mg of propylthiouracil ($C_7H_{10}N_2OS$).

Acceptance criteria: 98.0%–100.5% on the dried basis

IMPURITIES

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

Delete the following:

- ▲• **[SELENIUM \(291\)](#).**

Sample: 200 mg

Acceptance criteria: 0.003%▲ (USP 1-May-2022)

- **[ORDINARY IMPURITIES \(466\)](#).**

Solvent: Methanol

Application volume: 10 µL

Eluant: Toluene, ethyl acetate, and formic acid (50:45:5) in a nonequilibrated chamber

Visualization: 1

Acceptance criteria: Meets the requirements

SPECIFIC TESTS

- **[MELTING RANGE OR TEMPERATURE \(741\)](#):** 218°–221°

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

Analysis: Dry at 105° for 2 h.

Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed, light-resistant 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	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. 46(5)

Current DocID: GUID-7E8B98DD-A362-44A5-972C-9FFA7B645C5A_5_en-US
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