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Propylthiouracil Compounded Oral Suspension

DEFINITION

Propylthiouracil Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of propylthiouracil ($C_7H_{10}N_2OS$).

Prepare Propylthiouracil Compounded Oral Suspension 5 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩).

Propylthiouracil tablets[a] equivalent to	500 mg of propylthiouracil
Vehicle: a 1:1 mixture of Ora-Sweet[b] and Ora-Plus,[b] a sufficient quantity to make	100 mL

[a] Propylthiouracil 50-mg tablets, West-Ward Pharmaceutical Corp., Eatontown, NJ.

[b] Paddock Laboratories, Minneapolis, MN.

Calculate the required quantity of each ingredient for the total amount to be prepared. Place the required number of *Propylthiouracil tablets* in a suitable mortar, and comminute to a fine powder with a pestle. Add the *Vehicle* in small portions, and triturate to make a smooth paste. Add increasing volumes of the *Vehicle* to make a propylthiouracil liquid that is pourable. Transfer the contents of the mortar, stepwise and quantitatively, to a calibrated bottle. Add enough of the *Vehicle* to bring to final volume, and mix well.

ASSAY

Change to read:

• **Procedure**

Mobile phase: 5 mM 1-heptanesulfonic acid ▲sodium salt, glacial▲ (USP 1-Aug-2020) acetic acid (1% v/v), and methanol (40:45:15). Pass through a nylon 66 filter of 0.45-µm pore size, and degas.

Internal standard solution: 1.0 mg/mL of 6-methyl-2-thiouracil in methanol

Standard stock solution: 1.75 mg/mL of USP Propylthiouracil RS in methanol

Standard solution: Pipet 0.4 mL of the *Standard stock solution* into a 10-mL volumetric flask, and add 0.25 mL of the *Internal standard solution*. Dilute with *Mobile phase* to volume to obtain a nominal concentration of 70 µg/mL of propylthiouracil and 25 µg/mL of 6-methyl-2-thiouracil, and centrifuge.

Sample solution: Shake thoroughly by hand each bottle of Oral Suspension. Pipet 2 mL of Oral Suspension into a 10-mL volumetric flask, and dilute with methanol to volume to obtain a concentration of 1 mg/mL. Transfer 0.7 mL of the diluted solution to a 10-mL volumetric flask, and add 0.25 mL of the *Internal standard solution*. Dilute with *Mobile phase* to volume to obtain a nominal concentration of 70 µg/mL of propylthiouracil and 25 µg/mL of 6-methyl-2-thiouracil, and centrifuge.

Chromatographic system

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

Mode: LC

Detector: UV 276 nm

Column: 3.0-mm × 15-cm; 5-µm packing L1

Column temperature: 40°

Flow rate: 0.4 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[Note—The relative retention times for 6-methyl-2-thiouracil and propylthiouracil are about 0.25 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 10.0 between propylthiouracil and 6-methyl-2-thiouracil

Column efficiency: NLT 10,000 theoretical plates

Tailing factor: NMT 2.0 for the propylthiouracil peak

Relative standard deviation: NMT 2.0% for replicate injections

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 Oral Suspension taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = peak response ratio of propylthiouracil to the internal standard from the *Sample solution*

R_S = peak response ratio of propylthiouracil to the internal standard 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: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 3.8–4.8

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistant containers. Store at controlled room temperature or in a refrigerator.

• **Beyond-Use Date:** NMT 90 days after the date on which it was compounded, when stored in a refrigerator, and NMT 60 days after the date on which it was compounded, when stored at controlled room temperature

• **Labeling:** Label it to indicate that it is to be well shaken before use, and to state the *Beyond-Use Date*.

• **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 COMPOUNDED ORAL SUSPENSION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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