Status: Currently Official on 15-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-CA0165E0-424C-4C6B-BD7A-CFDFF532A20C_1_en-US
DOI: https://doi.org/10.31003/USPNF_M45015_01_01
DOI Ref: 89d79

Levothyroxine Sodium Oral Powder

» Levothyroxine Sodium Oral Powder contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of levothyroxine sodium ($C_{15}H_{10}I_4NNaO_4$).

Packaging and storage—Preserve in tight, light-resistant containers.

Labeling—Label it to indicate that it is for veterinary use only.

USP Reference standards ⟨11⟩—
USP Levothyroxine RS

Identification—The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation,* as obtained in the *Assay*.

Loss on drying ⟨731⟩—Dry it in vacuum at 60° for 3 hours: it loses not more than 2.0% of its weight.

Assay—

Mobile phase—Prepare a filtered and degassed mixture of water and acetonitrile (65:35) that contains 1 mL of phosphoric acid in each 1000 mL. Make adjustments if necessary (see *System Suitability* under *Chromatography ⟨621⟩*).

0.01 M Methanolic sodium hydroxide—Dissolve 400 mg of sodium hydroxide in 500 mL of water. Cool, add 500 mL of methanol, and mix.

Standard preparation—Dissolve an accurately weighed quantity of USP Levothyroxine RS in *0.01 M Methanolic sodium hydroxide*, and dilute quantitatively and stepwise with *0.01 M Methanolic sodium hydroxide* to obtain a solution having a known concentration of about 4 µg per mL.

Assay preparation—Transfer an accurately weighed portion of Oral Powder, equivalent to about 5 mg of levothyroxine sodium, to a 250-mL volumetric flask. Dilute with *0.01 M Methanolic sodium hydroxide* to volume, mix, and allow to stand for 4 hours, with occasional mixing. Pass a portion of this mixture through a filter that does not absorb levothyroxine. Transfer 10.0 mL of the filtrate to a 50-mL volumetric flask, dilute with *0.01 M Methanolic sodium hydroxide* to volume, and mix.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 225-nm detector and a 4.6-mm × 25-cm column that contains packing L10. The flow rate is about 1 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the tailing factor is not more than 1.8; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 50 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of levothyroxine sodium ($C_{15}H_{10}I_4NNaO_4$) in the portion of Oral Powder taken by the formula:

$$(798.85/776.87)(1.25C)(r_U/r_S)$$

in which 798.85 and 776.87 are the molecular weights of levothyroxine sodium and levothyroxine, respectively; C is the concentration, in µg per mL, of USP Levothyroxine RS in the *Standard preparation;* and r_U and r_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.

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

Topic/Question	Contact	Expert Committee
LEVOTHYROXINE SODIUM ORAL POWDER	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. PF 34(4)

Current DocID: GUID-CA0165E0-424C-4C6B-BD7A-CFDFF532A20C_1_en-US

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