Status: Currently Official on 15-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-12E4D55A-F077-4D01-B358-10FE264C82EF_1_en-US
DOI: https://doi.org/10.31003/USPNF_M45510_01_01
DOI Ref: hsc8i

Liothyronine Sodium Tablets

» Liothyronine Sodium Tablets contain an amount of $C_{15}H_{11}I_3NNaO_4$ equivalent to not less than 90.0 percent and not more than 110.0 percent of the labeled amount of liothyronine ($C_{15}H_{12}I_3NO_4$).

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩—

USP Levothyroxine RS
USP Liothyronine RS

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

Dissolution ⟨711⟩—[Note—All containers that are in contact with solutions containing liothyronine sodium are to be made of glass.]

Medium: pH 10.0 ± 0.05 alkaline borate buffer (see *Buffer Solutions* in the section *Reagents, Indicators, and Solutions*); 250 mL.

Apparatus 3: 30 dips per minute, using 20-mesh screen on the top and 40-mesh screen on the bottom of the glass reciprocating cylinder.

Time: 45 minutes.

Determine the amount of liothyronine sodium ($C_{15}H_{12}I_3NO_4$) dissolved by employing the following method.

Ammoniated solution—Add 0.05 mL of ammonium hydroxide to 200 mL of water.

Mobile phase—Prepare a filtered and degassed mixture of water and acetonitrile (55:45) that contains 1 mL of phosphoric acid in each 1000 mL of solution. Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard solution—Dissolve an accurately weighed quantity of USP Liothyronine RS in *Ammoniated solution*, and dilute quantitatively, and stepwise if necessary, with *Ammoniated solution* to obtain a solution having a known concentration of about 10 µg of USP Liothyronine RS per mL. Dilute a portion of this solution quantitatively, and stepwise if necessary, with water to obtain a solution having a known concentration of about 0.5 µg of USP Liothyronine RS per mL.

Test solution—Transfer 20 mL of the solution under test to a centrifuge tube, and centrifuge until a clear supernatant is obtained.

Resolution solution—Prepare a solution of USP Liothyronine RS and USP Levothyroxine RS in *Ammoniated solution* having known concentrations of about 10 µg of each USP Reference Standard per mL. Dilute with water to obtain a concentration of about 0.5 µg of each USP Reference Standard per mL.

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 2 mL per minute. Chromatograph the *Resolution solution*, and record the peak responses as directed for *Procedure:* the resolution, *R,* between liothyronine and levothyroxine is not less than 3.0. Chromatograph the *Standard solution*, and record the peak responses as directed for *Procedure:* the relative standard deviation for replicate injections is not more than 4.0%.

Procedure—Separately inject equal volumes (about 200 µL) of the *Standard solution* and the *Test solution* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the amount of $C_{15}H_{12}I_3NO_4$ dissolved.

Tolerances—Not less than 70% *(Q)* of the labeled amount of $C_{15}H_{12}I_3NO_4$ is dissolved in 45 minutes.

Uniformity of dosage units ⟨905⟩: meet the requirements.

Assay—

Mobile phase, Standard preparation, and *Chromatographic system*—Proceed as directed in the *Assay* under *Liothyronine Sodium*.

Assay preparation—Weigh and finely powder not fewer than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 100 µg of liothyronine sodium, to a centrifuge tube, add 2 glass beads, pipet 10 mL of *Mobile phase* into the tube, and mix using a vortex mixer for 3 minutes. Centrifuge to obtain a clear supernatant, filtering if necessary.

Procedure—Proceed as directed in the *Assay* under *Liothyronine Sodium*. Calculate the quantity, in µg, of liothyronine ($C_{15}H_{12}I_3NO_4$) in the portion of Tablets taken by the formula:

$$10C(r_U/r_S)$$

in which *C* is the concentration, in µg per mL, of USP Liothyronine RS in the *Standard preparation;* and r_U and r_S are the liothyronine 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
LIOTHYRONINE SODIUM 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. PF 34(4)

Current DocID: GUID-12E4D55A-F077-4D01-B358-10FE264C82EF_1_en-US
DOI: https://doi.org/10.31003/USPNF_M45510_01_01
DOI ref: hsc8i