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Add the following:

Liothyronine Sodium Injection

DEFINITION

Liothyronine Sodium Injection contains an amount of liothyronine sodium ($C_{15}H_{11}I_3NNaO_4$) equivalent to NLT 90.0% and NMT 115.0% of the labeled amount of liothyronine ($C_{15}H_{12}I_3NO_4$).

IDENTIFICATION

- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Solutions containing liothyronine should be protected from light.

Buffer: 5.8 g/L of [dibasic sodium phosphate anhydrous](#) and 3.5 g/L of [monobasic potassium phosphate, anhydrous](#) in [water](#). Adjust with [phosphoric acid](#) to a pH of 3.0.

Mobile phase: [Methanol](#) and *Buffer* (55:45)

Diluent: Dilute hydrochloric acid in [water](#) (1:50), and then add the same volume of [methanol](#).

Standard solution: 1 µg/mL of [USP Liothyronine RS](#) in *Diluent*

Sample solution: Nominally 1 µg/mL of liothyronine from Injection in *Diluent*

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 225 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.

Column: 4-mm × 8-cm; 5-µm packing [L7](#)

Flow rate: 1.25 mL/min

Injection volume: 20 µL

Run time: NLT 2.5 times the retention time of liothyronine

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of liothyronine ($C_{15}H_{12}I_3NO_4$) in the portion of Injection taken:

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

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

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

C_S = concentration of [USP Liothyronine RS](#) in the *Standard solution* (µg/mL)

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

Acceptance criteria: 90.0%–115.0%

IMPURITIES• **ORGANIC IMPURITIES**

Solutions containing liothyronine should be protected from light.

Solution A: 4.9 g/L of [sulfamic acid](#) and 0.8 g/L of sodium hydroxide in [water](#). Adjust with [10 N sodium hydroxide TS](#) to a pH of 2.0.

Solution B: [Acetonitrile](#)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	90	10
3	90	10
6	70	30
14	70	30
44	20	80
54	20	80
56	90	10
60	90	10

Diluent: 0.175 g/L of citric acid, anhydrous, 71.5 mL/L of [absolute alcohol](#), and 8.5 mL/L of [ammonium hydroxide](#) in [water](#) prepared as follows. Transfer an appropriate amount of citric acid, anhydrous to a suitable flask and dissolve in 20% of the flask volume of [water](#). To this solution, add appropriate amounts of [absolute alcohol](#) and [ammonium hydroxide](#), and then dilute with [water](#) to volume.

Standard solution: 0.03 µg/mL of [USP Liothyronine RS](#) in *Diluent*. Sonicate to dissolve, if necessary.

Sensitivity solution: 0.01 µg/mL of [USP Liothyronine RS](#) from the *Standard solution* in *Diluent*

Sample solution: Nominally 10 µg/mL of liothyronine from Injection

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 225 nm

Column: 4-mm × 15-cm; 3-µm packing [L1](#)

Flow rate: 1 mL/min

Injection volume: 150 µL

System suitability

Samples: *Standard solution* and *Sensitivity solution*

[NOTE—The relative retention times in [Table 2](#) are provided as information that could aid in peak assignment.]

Table 2

Name	Relative Retention Time
Diiodotyrosine ^a	0.4
Diiodothyronine ^b	0.6
Liothyronine	1.0



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