Status: Currently Official on 15-Feb-2025
Official Date: Official as of 19-Jun-2024
Document Type: USP Monographs
DocId: GUID-A2F8B679-8CD7-4471-B46E-69917C6D8D73_2_en-US
DOI: https://doi.org/10.31003/USPNF_M45700_02_01
DOI Ref: imi6y

Lithium Oral Solution

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click www.uspnf.com/rb-lithium-os-20240628.

Change to read:

DEFINITION

Lithium Oral Solution is prepared ▲either▲ (RB 19-Jun-2024) from Lithium Citrate or ▲from▲ (RB 19-Jun-2024) Lithium Hydroxide ▲or Lithium Carbonate▲ (RB 19-Jun-2024) to which an excess of Citric Acid has been added. It contains NLT 90.0% and NMT 110.0% of the labeled amount of lithium (Li).

IDENTIFICATION

- **A.** The emission intensity at 671 nm of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.
- **B.** **Identification Tests—General, *Citrate* (191):** Meets the requirements

ASSAY

- **Procedure**

Surfactant solution: 1%–2% solution of nonionic surfactant, such as t-dodecyl mercaptan ethoxylate or polyoxyethylene (20) sorbitan monolaurate, in water

Standard stock solution: 0.3 mg/mL of USP Lithium Carbonate RS prepared as follows. Transfer the required quantity of USP Lithium Carbonate RS to a suitable volumetric flask, and add 20% of the flask volume of water and 0.5% of the flask volume of hydrochloric acid. Shake until dissolved.

Standard solution: 6 µg/mL of USP Lithium Carbonate RS from the *Standard stock solution* prepared as follows. Transfer a suitable volume of the *Standard stock solution* to a suitable volumetric flask. Add 80% of the flask volume of water and 2% of the flask volume of *Surfactant solution*, and dilute with water to volume. Determine the pH of the solution.

Sample stock solution: Nominally 0.06 mg/mL of lithium in water prepared as follows. Transfer a volume of Oral Solution equivalent to NLT 60 mg of lithium to a suitable volumetric flask. Dilute with water to volume.

Sample solution: Nominally 1.2 µg/mL of lithium from the *Sample stock solution* prepared as follows. Transfer a suitable volume of the *Sample stock solution* to a suitable volumetric flask. Add 95% of the flask volume of water, 0.2% of the flask volume of 1 N hydrochloric acid, and 2% of the flask volume of the *Surfactant solution*. Adjust with 1 N hydrochloric acid or 1 N sodium hydroxide to the same pH (±0.1 pH unit) as that of the *Standard solution*, and dilute with water to volume.

Blank: *Surfactant solution*

Instrumental conditions

Mode: Flame photometry

Analytical wavelength: About 671 nm

Analysis

Samples: *Standard solution*, *Sample solution*, and *Blank*

Use the *Blank* to zero the instrument. Measure the emission responses for the *Standard solution* and *Sample solution*. Calculate the percentage of the labeled amount of lithium (Li) in the portion of Oral Solution taken:

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

r_U = photometer reading of the *Sample solution*

r_S = photometer reading of the *Standard solution*

C_S = concentration of USP Lithium Carbonate RS in the *Standard solution* (µg/mL)

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

A_r = atomic weight of lithium, 6.94

M_r = molecular weight of lithium carbonate, 73.89

F = number of lithium ions in one mole of lithium carbonate, 2

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Uniformity of Dosage Units ⟨905⟩:** Meets the requirements for oral solution packaged in single-unit containers

SPECIFIC TESTS

• **pH ⟨791⟩:** 4.0–5.0

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers. Store at controlled room temperature.

• **USP Reference Standards ⟨11⟩**

USP Lithium Carbonate RS

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

Topic/Question	Contact	Expert Committee
LITHIUM ORAL SOLUTION	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 39(4)

Current DocID: GUID-A2F8B679-8CD7-4471-B46E-69917C6D8D73_2_en-US

DOI: https://doi.org/10.31003/USPNF_M45700_02_01

DOI ref: imi6y