



Lithium Oral Solution

Type of Posting	Revision Bulletin
Posting Date	18-Jun-2024
Official Date	19-Jun-2024
Expert Committee	Small Molecules 4

In accordance with the Rules and Procedures of the Council of Experts, the Small Molecules 4 Expert Committee has revised the Lithium Oral Solution monograph. The purpose of this revision is to add "Lithium Carbonate" in the *Definition* to allow flexibility and to accommodate FDA-approved drug products with different formulations.

The Lithium Oral Solution Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact V. Durga Prasad, Senior Scientist II, (+91 40 4448 8723 or durgaprasad.v@usp.org).

Lithium Oral Solution

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](#)
-
-

Page Information:

Not Applicable

Current DocID:

© 2024 The United States Pharmacopeial Convention *All Rights Reserved.*