



## Lithium Oral Solution

<b>Type of Posting</b>	Notice of Intent to Revise
<b>Posting Date</b>	17-Nov-2023
<b>Targeted Official Date</b>	To Be Determined, Revision Bulletin
<b>Expert Committee</b>	Small Molecules 4

In accordance with the Rules and Procedures of the Council of Experts and the Pending Monograph Guideline, this is to provide notice that the Small Molecules 4 Expert Committee intends to revise the Lithium Oral Solution monograph.

Based on the supporting data received from a manufacturer awaiting FDA approval, the Expert Committee proposes to revise the Lithium Oral Solution monograph to add “Lithium Carbonate” in the *Definition* to allow flexibility and to accommodate FDA-approved drug products with different formulations.

The proposed revision is contingent on FDA approval of a product that meets the proposed monograph specifications. The proposed revision will be published as a Revision Bulletin and an official date will be assigned to coincide as closely as possible with the FDA approval of the associated product.

See below for additional information about the proposed text.<sup>1</sup>

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

---

<sup>1</sup> This text is not the official version of a *USP–NF* monograph and may not reflect the full and accurate contents of the currently official monograph. Please refer to the current edition of the *USP–NF* for official text.

USP provides this text to indicate changes that we anticipate will be made official once the product subject to this proposed revision under the Pending Monograph Program receives FDA approval. Once FDA approval is granted for the associated revision request, a Revision Bulletin will be posted that will include the changes indicated herein, as well as any changes indicated in the product’s final approval, combined with the text of the monograph as effective on the date of approval. Any revisions made to a monograph under the Pending Monograph Program that are posted without prior publication for comment in the *Pharmacopeial Forum* must also meet the requirements outlined in the [USP Guideline on Use of Accelerated Processes for Revisions to the USP–NF](#).

## Lithium Oral Solution

### Change to read:

#### DEFINITION

Lithium Oral Solution is prepared either (TBD) from Lithium Citrate or from (TBD) Lithium Hydroxide or Lithium Carbonate (TBD) 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 ( $\pm 0.1$  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:

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