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Lithium Carbonate Capsules

DEFINITION

Lithium Carbonate Capsules contain NLT 95.0% and NMT 105.0% of the labeled amount of lithium carbonate (Li_2CO_3).

IDENTIFICATION

- **A.** A portion of the Capsule contents effervesces upon the addition of an acid, yielding a colorless gas that, when passed into calcium hydroxide TS, immediately forms a white precipitate.
- **B.** The emission intensity at 671 nm of the *Sample solution* corresponds to that of the *Standard solution* as obtained in the Assay.

ASSAY

PROCEDURE

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

Blank: *Surfactant solution* and water (1:50)

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 water to 20% of the flask volume and hydrochloric acid to 0.5% of the flask volume. Shake until dissolved, and dilute with water to volume.

Standard solution: 0.006 mg/mL of [USP Lithium Carbonate RS](#) from *Standard stock solution* prepared as follows. Pipet a suitable volume of *Standard stock solution* into a suitable volumetric flask. Add water to 80% of the flask volume and *Surfactant solution* to 2% of the flask volume, and dilute with water to volume.

Sample stock solution: Nominally 0.6 mg/mL of lithium carbonate from the contents of NLT 20 Capsules prepared as follows. Transfer a portion of powder, equivalent to NLT 600 mg of lithium carbonate, into a suitable volumetric flask. Add water to 4% of the flask volume and hydrochloric acid to 0.5% of the flask volume, shake until the solid is well disintegrated, and dilute with water to volume.

Sample solution: Nominally 0.006 mg/mL of lithium carbonate from *Sample stock solution* prepared as follows. Pipet a suitable volume of *Sample stock solution* into a suitable volumetric flask. Add water to 80% of the flask volume and *Surfactant solution* to 2% of the flask volume, and dilute with water to volume.

Instrumental conditions

Mode: Flame photometry

Analytical wavelength: About 671 nm

Analysis

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

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 carbonate (Li_2CO_3) in the portion of Capsules taken:

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

r_U = emission response from the *Sample solution*

r_S = emission response from the *Standard solution*

C_S = concentration of [USP Lithium Carbonate RS](#) in the *Standard solution* (mg/mL)

C_U = nominal concentration of the *Sample solution* (mg/mL)

Acceptance criteria: 95.0%–105.0%

PERFORMANCE TESTS

- [DISSOLUTION \(711\)](#)

Medium: Water; 900 mL

Apparatus 1: 100 rpm

Time: 30 min

Surfactant solution, Blank, and Standard solution: Prepare as directed in the Assay.

Sample solution: Pass the solution under test through a suitable filter. Transfer 20.0 mL of the filtrate to a 1000-mL volumetric flask. Add 500 mL of water, 1 drop of hydrochloric acid, and 20 mL of *Surfactant solution*. Dilute with water to volume.

Analysis

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

Use the *Blank* to zero the instrument. Measure the emission responses for the *Standard solution* and *Sample solution*.

Calculate percentage of the labeled amount of lithium carbonate (Li_2CO_3) dissolved:

$$\text{Result} = (r_U/r_S) \times C_S \times V \times D \times (1/L) \times 100$$

r_U = emission response from the *Sample solution*

r_S = emission response from the *Standard solution*

C_S = concentration of [USP Lithium Carbonate RS](#) in the *Standard solution* (mg/mL)

V = volume of the *Medium*, 900 mL

D = dilution factor

L = label claim (mg/Capsule)

Tolerances: NLT 80% (Q) of the labeled amount of lithium carbonate (Li_2CO_3) is dissolved.

- [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed 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 CARBONATE CAPSULES	Documentary Standards Support	SM42020 Small Molecules 4
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

Chromatographic Database Information: [Chromatographic Database](#)

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