Sodium—

Standard preparation—Dissolve 1.271 g of sodium chloride, previously dried at 130° to constant weight, in water in a 1000-mL volumetric flask, dilute with water to volume, and mix. Each mL contains 500 µg of Na.

Stock solution—Suspend 20.0 g of Lithium Carbonate in 100 mL of water, cautiously add 50.0 mL of hydrochloric acid, transfer to a 200-mL volumetric flask, dilute with water to volume, and mix.

Test preparation—Pipet 5 mL of *Stock solution* into a 100-mL volumetric flask, add water to volume, and mix.

Control solution—Pipet 5 mL of *Stock solution* and 1 mL of *Standard preparation* into a 100-mL volumetric flask, add water to volume, and mix.

Procedure—Set a suitable flame photometer for maximum emission at about 589 nm, using the *Control solution*. Measure the emission intensities of the *Test preparation* at 580 nm and 589 nm. The difference between the intensities observed at 580 nm and 589 nm for the *Test preparation* does not exceed the difference between the intensities observed at 589 nm for the *Test preparation* and the *Control solution*, respectively. The sodium limit is 0.1%.

Heavy metals ⟨231⟩**—**Dissolve 1 g in 10 mL of 3 N hydrochloric acid, and dilute with water to 25 mL: the limit is 0.002%.

Assay—Dissolve about 1 g of Lithium Carbonate, accurately weighed, in 50.0 mL of 1 N sulfuric acid VS, add methyl orange TS, and titrate the excess acid with 1 N sodium hydroxide VS. Perform a blank determination (see *Residual Titrations* under *Titrimetry* ⟨541⟩). Each mL of 1 N sulfuric acid is equivalent to 36.95 mg of Li_2CO_3.

Lithium Carbonate Capsules

» Lithium Carbonate Capsules contain not less than 95.0 percent and not more than 105.0 percent of the labeled amount of Li_2CO_3.

Packaging and storage—Preserve in well-closed containers.

USP Reference standards ⟨11⟩**—**
USP Lithium Carbonate RS

Identification—A portion of the Capsule contents responds to the *Identification* tests under *Lithium Carbonate*.

Dissolution ⟨711⟩**—**

Medium: water; 900 mL.

Apparatus 1: 100 rpm.

Time: 30 minutes.

Procedure—Determine the amount of Li_2CO_3 dissolved in filtered portions of the solution under test with a suitable flame photometer, as directed in the *Assay*.

Tolerances—Not less than 80% *(Q)* of the labeled amount of Li_2CO_3 is dissolved in 30 minutes.

Uniformity of dosage units ⟨905⟩: meet the requirements.

Assay—

Standard preparation—Transfer to a 100-mL volumetric flask about 30 mg of USP Lithium Carbonate RS, accurately weighed. Add about 20 mL of water and 0.5 mL of hydrochloric acid, shake until dissolved, dilute with water to volume, and mix. Pipet 20 mL of the resulting solution into a 1000-mL volumetric flask, add about 800 mL of water and 20 mL of a suitable surfactant solution, appropriately diluted, dilute with water to volume, and mix.

Assay preparation—Empty as completely as possible the contents of not less than 20 Capsules. Weigh accurately a portion of the powder, equivalent to about 600 mg of lithium carbonate, and transfer to a 1000-mL volumetric flask. Add 40 mL of water and 5 mL of hydrochloric acid, shake until the sample is well disintegrated, dilute with water to volume, and mix. Pipet 10 mL of the resulting solution into a 1000-mL volumetric flask, add about 800 mL of water and 20 mL of the surfactant solution, dilute with water to volume, and mix.

Procedure—Employ a suitable flame photometer, and adjust the instrument with the surfactant solution. Aspirate into the photometer the *Standard preparation* and the *Assay preparation*, and measure the emission at about 671 nm. Calculate the quantity, in mg, of Li_2CO_3 in the portion of Capsules taken by the formula:

$$100C(A / S)$$

in which *C* is the concentration, in µg per mL, of USP Lithium Carbonate RS in the *Standard preparation;* and *A* and *S* are the photometer readings of the *Assay preparation* and the *Standard preparation*, respectively.

Lithium Carbonate Tablets

DEFINITION

Lithium Carbonate Tablets contain NLT 95.0% and NMT 105.0% of the labeled amount of Li_2CO_3.

IDENTIFICATION

A portion of the powdered Tablets meets the requirements of the following tests.

- **A.** It effervesces upon the addition of an acid, yielding a colorless gas that, when passed into calcium hydroxide TS, immediately causes a white precipitate to form.
- **B.** When moistened with hydrochloric acid, it imparts an intense crimson color to a nonluminous flame.

ASSAY

- **PROCEDURE**

Standard solution: Transfer 30 mg of USP Lithium Carbonate RS to a 100-mL volumetric flask, and add 20 mL of water and 0.5 mL of hydrochloric acid. Shake until dissolved, and dilute with water to volume. Pipet 20 mL of the resulting solution into a 1000-mL volumetric flask, add 800 mL of water and 20 mL of a suitable surfactant solution, and dilute with water to volume.

Sample solution: Powder NLT 20 Tablets. Transfer a portion of powder, nominally equivalent to 600 mg of lithium carbonate, into a 1000-mL volumetric flask. Add 40 mL of water and 5 mL of hydrochloric acid, shake until the solid is well disintegrated, and dilute with water to volume. Pipet 10 mL of the resulting solution into a 1000-mL volumetric flask, add 800 mL of water and 20 mL of the surfactant solution, and dilute with water to volume.

Spectrometric conditions

Mode: Flame photometer

Analytical wavelength: About 671 nm

[NOTE—Adjust the instrument with the surfactant solution.]

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of Li_2CO_3 in the portion of Tablets taken:

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

r_U = peak response from the *Sample solution*
r_S = peak response from the *Standard solution*
C_S = concentration of the *Standard solution* (mg/mL)
C_U = nominal concentration of lithium carbonate in the *Sample solution* (mg/mL)

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Acceptance criteria: 95.0%–105.0%

PERFORMANCE TESTS

• **DISSOLUTION** ⟨**711**⟩
Medium: Water; 900 mL
Apparatus 1: 100 rpm
Time: 30 min
Surfactant solution: Nonoxynol-9 in water (1:1) v/v
Standard solution: Transfer 30 mg of USP Lithium Carbonate RS to a 100-mL volumetric flask. Add 20 mL of water and 0.5 mL of hydrochloric acid, shake until dissolved, and dilute with water to volume. Pipet 20 mL of the resulting solution into a 1000-mL volumetric flask, add 800 mL of water and 20 mL of a suitable surfactant solution, and dilute with water to volume.
Sample solution: Dilute 900 mL of the solution under test with *Medium* to 1000 mL. Pass 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: *Standard solution* and *Sample solution*
Determine the percentage of Li_2CO_3 dissolved:

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

r_U = peak response from the *Sample solution*
r_S = peak 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)

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

• **UNIFORMITY OF DOSAGE UNITS** ⟨**905**⟩**:** Meet the requirements

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in well-closed containers.
• **USP REFERENCE STANDARDS** ⟨**11**⟩
USP Lithium Carbonate RS

Lithium Carbonate Extended-Release Tablets

» Lithium Carbonate Extended-Release Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of lithium carbonate (Li_2CO_3).

Packaging and storage—Preserve in well-closed containers.

Labeling—The labeling indicates the *Dissolution Test* with which the product complies.

USP Reference standards ⟨11⟩**—**
USP Lithium Carbonate RS

Identification—A portion of powdered Tablets responds to the *Identification* tests under *Lithium Carbonate.*

Uniformity of dosage units ⟨905⟩**:** meet the requirements.

Dissolution ⟨711⟩**—**

TEST 1—If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 1.*

Medium: dilute hydrochloric acid (7 in 1000); 800 mL.

Apparatus 1: 100 rpm.

Times: 15, 45, 90, and 120 minutes.

Procedure—At each *Time,* withdraw 8.0 mL of the solution under test, and pass through a filter having a 35-µm or finer porosity. Using the filtrate as the *Assay preparation,* suitably diluted with *Medium* if necessary, and using *Medium* to prepare the *Standard preparation,* determine the amount of Li_2CO_3 dissolved by employing a flame photometer, as directed in the *Assay.*

Tolerances—The percentages of the labeled amount of Li_2CO_3 dissolved at the specified times conform to *Acceptance Table 2.*

Time (minutes)	Amount dissolved
15	between 2% and 16%
45	between 25% and 45%
90	between 60% and 85%
120	not less than 85%

TEST 2—If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2.*

Apparatus and *Procedure*—Proceed as directed for *Test 1.*

Medium: water; 900 mL.

Times: 1, 3, and 7 hours.

Tolerances—The percentages of the labeled amount of Li_2CO_3 dissolved at the specified times conform to *Acceptance Table 2.*

Time (hours)	Amount dissolved
1	not more than 40%
3	between 45% and 75%
7	not less than 70%

TEST 3—If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 3.*

Medium: water; 250 mL.

Apparatus 3: 6 dips per minute, 20-mesh top screen and 100-mesh bottom screen.

Procedure—Proceed as directed for *Test 1.*

Times and *Tolerances*—The percentages of the labeled amount of Li_2CO_3 dissolved at the specified times conform to *Acceptance Table 2.*

Time (hours)	Amount dissolved
1	between 10% and 45%
2	between 25% and 75%
6	not less than 70%

TEST 4—If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 4.*

Medium, Apparatus, Times, and *Procedure*—Proceed as directed for *Test 1.*

Tolerances—The percentages of the labeled amount of Li_2CO_3dissolved at the specified times conform to *Acceptance Table 2.*

Time (minutes)	Amount dissolved
15	not more than 15%
45	between 20% and 45%
90	between 50% and 80%
120	not less than 70%

TEST 5—If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 5.*

Medium: water; 900 mL.

Apparatus 1: 100 rpm.

Times: 30, 90, and 150 minutes.

Procedure—Pass a portion of the solution under test through a 0.8-µm mixed cellulose esters filter, discarding the first 10 mL of the filtrate. Using the rest of the filtrate as the *Assay preparation,* suitably diluted with *Medium* if necessary, and using *Medium* to prepare the *Standard preparation,* determine the amount of Li_2CO_3 dissolved by employing a flame photometer, as directed in the *Assay.*

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