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# Lithium Carbonate Extended-Release Tablets

## DEFINITION

Lithium Carbonate Extended-Release Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of lithium carbonate ( $\text{Li}_2\text{CO}_3$ ).

## IDENTIFICATION

- **A.** A portion of powdered Tablets 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

**Diluent:** Dilute 5 mL of hydrochloric acid with water to 1 L.

**Standard solution:** 0.3 mg/mL of [USP Lithium Carbonate RS](#) in *Diluent* prepared as follows. Transfer a suitable quantity of [USP Lithium Carbonate RS](#) to an appropriate volumetric flask. 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.

**Sample stock solution:** Nominally 12 mg/mL of lithium carbonate from a number of Tablets, nominally equivalent to NLT 1200 mg of lithium carbonate prepared as follows. Transfer the required number of Tablets to a suitable container. Add the required amount of *Diluent*. Shake until completely dissolved. Filter, and discard the first 25 mL. Use the remaining filtrate.

**Sample solution:** Nominally 0.3 mg/mL from *Sample stock solution* in *Diluent*

[NOTE—The *Standard solution* and *Sample solution* may be diluted quantitatively with *Diluent*, if necessary, to yield solutions of suitable concentrations adaptable to the linear or working range of the instrument.]

### Instrumental conditions

**Mode:** Flame photometry

**Analytical wavelength:** About 671 nm

### Analysis

**Samples:** *Standard solution* and *Sample solution*

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

Calculate the percentage of labeled amount of lithium carbonate ( $\text{Li}_2\text{CO}_3$ ) in the portion of Tablets:

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

$r_U$  = 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 lithium carbonate in the *Sample solution* (mg/mL)

$D$  = dilution factor, if needed

**Acceptance criteria:** 90.0%–110.0%

## PERFORMANCE TESTS

**Change to read:**

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

### Test 1

**Medium:** Dilute hydrochloric acid (7 in 1000); 800 mL

**Apparatus 1:** 100 rpm

**Time:** 15, 45, 90, and 120 min

**Standard solution:** [USP Lithium Carbonate RS](#) at a known concentration in *Medium*

**Sample solution:** At each time point  $i$ , withdraw 8.0 mL of the *Sample solution*, and pass through a filter of 35- $\mu\text{m}$  or finer pore size. Use the filtrate as the *Sample solution*, suitably diluted with *Medium* if necessary.

**Instrumental conditions**

**Mode:** Flame photometry

**Analytical wavelength:** About 671 nm

#### Analysis

**Samples:** *Standard solution and Sample solution*

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

Calculate the concentration,  $C_i$ , of lithium carbonate ( $\text{Li}_2\text{CO}_3$ ) in *Medium* (mg/mL) at each time point  $i$ :

$$C_i = (r_U/r_S) \times C_S$$

$r_U$  = 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)

Calculate the percentage of the labeled amount ( $Q$ ) of lithium carbonate ( $\text{Li}_2\text{CO}_3$ ) dissolved at each time point  $i$ :

$$\text{Result}_i = C_i \times V \times (1/L) \times 100$$

$$\text{Result}_i = \{C_i \times [V - (i - 1) \times V_S]\} + [(C_{i-1} + C_{i-2} \dots + C_1) \times V_S] \times (1/L) \times 100$$

$C_i$  = concentration of lithium carbonate in *Medium* in the portion of sample withdrawn at time point  $i$  (mg/mL)

$V$  = volume of *Medium*, ▲800▲ (ERR 1-Mar-2020) mL

$L$  = label claim (mg/Capsule)

$V_S$  = volume of the *Sample solution* withdrawn from the *Medium* (mL)

**Tolerances:** See [Table 1](#).

**Table 1**

| Time Point<br>(i) | Time<br>(min) | Amount Dissolved<br>(%) |
|-------------------|---------------|-------------------------|
| 1                 | 15            | 2–16                    |
| 2                 | 45            | 25–45                   |
| 3                 | 90            | 60–85                   |
| 4                 | 120           | NLT 85                  |

The percentages of the labeled amount of lithium carbonate ( $\text{Li}_2\text{CO}_3$ ) dissolved at the times specified conform to *Acceptance Table 2* in

[Dissolution \(711\)](#).

**Test 2:** If the product complies with this procedure, the labeling indicates that it meets *USP Dissolution Test 2*.

**Medium:** Water; 900 mL

**Apparatus 1:** 100 rpm

**Time:** 1, 3, and 7 h

**Standard solution, Sample solution, Instrumental conditions, and Analysis:** Proceed as directed in *Test 1*.

Calculate the percentage of the labeled amount of lithium carbonate ( $\text{Li}_2\text{CO}_3$ ) dissolved at each time point as described in *Test 1*.

**Tolerances:** See [Table 2](#).

**Table 2**

| Time Point<br>(i) | Time<br>(h) | Amount Dissolved<br>(%) |
|-------------------|-------------|-------------------------|
| 1                 | 1           | NMT 40                  |
| 2                 | 3           | 45–75                   |
| 3                 | 7           | NLT 70                  |



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