Lithium Carbonate Tablets

炭酸リチウム錠

Lithium Carbonate Tablets contain not less than 95.0% and not more than 105.0% of the labeled amount of lithium carbonate (Li_2CO_3: 73.89).

Method of preparation Prepare as directed under Tablets, with Lithium Carbonate.

Identification **(1)** Perform the test with powdered Lithium Carbonate Tablets as directed under Flame Coloration Test *<1.04>* (1): a persistent red color appears.

(2) To a quantity of powdered Lithium Carbonate Tablets, equivalent to 0.2 g of Lithium Carbonate, add 3 mL of dilute hydrochloric acid, shake thoroughly, add water to make 20 mL, and filter. To 5 mL of the filtrate add 2 mL each of sodium hydroxide TS and disodium hydrogen phosphate TS, warm and cool: a white precipitate is produced. To the precipitate add 2 mL of dilute hydrochloric acid: it dissolves.

(3) Weigh a quantity of powdered Lithium Carbonate Tablets, equivalent to 0.5 g of Lithium Carbonate, add 50 mL of water, shake thoroughly, and filter: the filtrate responds to Qualitative Tests *<1.09>* for carbonate.

Uniformity of dosage units *<6.02>* It meets the requirement of the Mass variation test.

Dissolution *<6.10>* When the test is performed at 100 revolutions per minute according to the Paddle method, using 900 mL of water as the dissolution medium, the dissolution rates in 15 minutes and in 180 minutes of a 100-mg tablet are not more than 45% and not less than 80%, respectively, and those in 30 minutes and in 180 minutes of a 200 mg-tablet are not more than 50% and not less than 80%, respectively.

Start the test with 1 tablet of Lithium Carbonate Tablets, withdraw exactly 20 mL of the medium at the specified minute after starting the test, and supply exactly 20 mL of water warmed to 37 ± 0.5℃ immediately after withdrawing of the medium every time. Filter the media through a membrane filter with a pore size not exceeding 0.45 μm. Discard not less than 10 mL of the first filtrate, pipet V mL of the subsequent filtrate, add exactly 5 mL of dilute hydrochloric acid, add water to make exactly V' mL so that each mL contains about 4.4 μg of lithium carbonate (Li_2CO_3), and use this solution as the sample solution. Separately, weigh accurately about 22 mg of lithium carbonate for assay, previously dried at 105℃ for 3 hours, and dissolve in water to make exactly 100 mL. Pipet 0.5 mL, 2 mL, 3 mL, 4 mL and 5 mL of this solution, add water to make them exactly 20 mL. Pipet 5 mL each of these solutions, add exactly 5 mL of dilute hydrochloric acid, add water to make them exactly 50 mL, and use these solutions as the standard solutions (1), (2), (3), (4) and (5), respectively. Perform the test with the sample solution and standard solutions as directed under Atomic Absorption Spectrophotometry *<2.23>* according to the following conditions. Determine the absorbances, $A_{T(n)}$, A_{S1}, A_{S2}, A_{S3}, A_{S4} and A_{S5}, and calculate the dissolution rates (%) using a calibration curve obtained from the absorbances of the standard solutions.

Dissolution rate (%) with respect to the labeled amount of lithium carbonate (Li_2CO_3) on the nth medium withdrawing (n = 1, 2)

$$= \left\{ \left(A_{T(n)} - \text{ordinate intercept of calibration curve} \right) + \sum_{i=1}^{n-1} \left(A_{T(i)} - \text{ordinate intercept of calibration curve} \right) \times \frac{1}{45} \right\} \times \frac{1}{\text{slope of calibration curve}} \times \frac{V'}{V} \times \frac{1}{C} \times 90$$

C: Labeled amount (mg) of lithium carbonate (Li_2CO_3) in 1 tablet

Gas: Combustible gas – Acetylene.
Supporting gas – Air.
Lamp: A lithium hollow-cathode lamp.
Wavelength: 670.8 nm.

Assay Weigh accurately the mass of not less than 20 tablets of Lithium Carbonate Tablets, and powder. Weigh accurately a portion of the powder, equivalent to about 1 g of lithium carbonate (Li_2CO_3), add exactly 100 mL of water and 50 mL of 0.5 mol/L sulfuric acid VS, remove carbon dioxide by gentle boiling, cool, and titrate *<2.50>* the excess sulfuric acid with 1 mol/L sodium hydroxide VS until the color of the solution changes from red to yellow (indicator: 3 drops of methyl red TS). Perform a blank determination in the same manner.

Each mL of 0.5 mol/L sulfuric acid VS
＝36.95 mg of Li_2CO_3

Containers and storage Containers－Well-closed containers.

Add the following to 9.41 Reagents, Test Solutions:

Lithium Carbonate for assay Li_2CO_3 [Same as the monograph Lithium Carbonate]