

Levocarnitine Tablets

Levocarnitine Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_7H_{15}NO_3$.

Packaging and storage— Preserve in tight containers.

Identification—

A: The retention time of the major peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the Standard preparation, as obtained in the Assay.

B: Dissolve 1 Tablet in 5 mL of water, filter, and add 5 mL of 1 N hydrochloric acid. Place 2 mL of the filtrate in a test tube and add a few drops of [ammonium reineckate TS](#): a red-violet precipitate is produced.

[Uniformity of dosage units](#) [905](#) : meet the requirements for Weight Variation.

[Dissolution](#) [711](#) —

Medium: water; 900 mL.

Apparatus 2: 75 rpm.

Time: 30 minutes.

Procedure— Determine the amount of $C_7H_{15}NO_3$ dissolved, employing the procedure set forth in the Assay, making any necessary modifications.

Tolerances— Not less than 75% (Q) of the labeled amount of $C_7H_{15}NO_3$ is dissolved in 30 minutes.

Assay—

pH 4.5 Phosphate buffer (0.05 M)—Dissolve 6.805 g of monobasic potassium phosphate in 1000 mL of water.

Mobile phase— Prepare a filtered and degassed mixture of acetonitrile and pH 4.5 Phosphate buffer (0.05 M) (65:35). Adjust with phosphoric acid to a pH of 4.7, and mix. Make adjustments if necessary.

Standard preparation— Dissolve an accurately weighed quantity of [USP Levocarnitine RS](#) in water to obtain a solution having a known concentration of about 3 mg per mL.

Resolution solution— Dissolve accurately weighed quantities of [USP Levocarnitine RS](#) and [USP Levocarnitine Related Compound A RS](#) in water to obtain a solution having concentrations of about 1.5 mg and 0.007 mg per mL, respectively.

Assay preparation— Transfer 10 Tablets, accurately weighed, to a 500-mL volumetric flask, and add water to volume. Shake until the Tablets have disintegrated completely, and pass through a filter having a 0.45- μ m porosity. Dilute the filtrate quantitatively with water to obtain a solution having a known concentration of about 3 mg of levocarnitine per mL.

Chromatographic system—The liquid chromatograph is equipped with a 205-nm detector and a 3.9-mm \times 30-cm column that contains 10- μ m packing L8. The flow rate is maintained at about 1 mL per minute. The chromatograph is programmed as follows. Initially elute 50 mL of acetonitrile, then change the composition linearly over the next 20 minutes to a mixture of 65% acetonitrile and 35% water. Elute 100 mL of this mixture, then change the composition linearly over the following 20 minutes to 100% Mobile phase, and allow chromatography to proceed for about 3 hours. Chromatograph the Resolution solution, and record the peak responses as directed for Procedure: the resolution, R, between crotonoylbetaine (levocarnitine related compound A) and levocarnitine is not less than 1.0. Chromatograph the Standard preparation, and record the peak responses as directed for Procedure: the relative standard deviation for replicate injections is not more than 2.0%.

Procedure— Separately inject equal volumes (about 20 μ L) of the Standard preparation and the Assay preparation into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of $C_7H_{15}NO_3$ in the portion of Tablets taken by the formula:

$$(L / D)(C)(r_U / r_S)$$

in which L is the labeled amount, in mg, of levocarnitine in each Tablet; D is the concentration, in mg per mL, of levocarnitine in the Assay preparation, based on the labeled quantity per Tablet and the extent of dilution; C is the concentration, in mg per mL, of [USP Levocarnitine RS](#) in the Standard preparation; and r_U and r_S are the peak responses obtained from the Assay preparation and the Standard preparation, respectively.