

Levocarnitine Oral Solution

Levocarnitine Oral Solution is a solution of Levocarnitine in water, and it contains suitable antimicrobial agents. It may contain a suitable flavor. It contains 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— The retention time of the major peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the Standard preparation, both relative to the internal standard, as obtained in the [Assay](#).

pH [791](#) : between 4.0 and 6.0.

Assay—

Phosphate buffer 0.05 M— Dissolve 11.5 mL of phosphoric acid in 1900 mL of water, adjust with about 100 mL of 1 N sodium hydroxide to a pH of 2.4, and mix.

Mobile phase— Dissolve 555 mg of sodium 1-heptanesulfonate in 980 mL of 0.05 M Phosphate buffer with stirring, add 20 mL of methanol, mix, degas, and filter. Make adjustments if necessary.

Internal standard solution— Transfer about 10 mg of p-aminobenzoic acid to a 100-mL volumetric flask, dissolve in water, dilute with water to volume, and mix. Transfer 5.0 mL of the resulting solution to a 25-mL volumetric flask, dilute with water to volume, and mix to obtain the Internal standard solution.

Standard preparation— Transfer an accurately weighed quantity of about 10 mg of [USP Levocarnitine RS](#) to a 5-mL volumetric flask, add 1.0 mL of Internal standard solution, dilute with water to volume, and mix.

Assay preparation— Transfer an accurately measured volume of Oral Solution, equivalent to about 500 mg of levocarnitine, to a 50-mL volumetric flask, dilute with water to volume, and mix. Wash a 10-mm × 4-cm disposable column containing 500 mg of packing L1, in the order, with two column volumes of methylene chloride, two column volumes of methanol, and three column volumes of water. Pipet 5.0 mL of the solution prepared above into the washed disposable column, and rinse the column twice with 6.0-mL portions of water. Collect the filtrate and washings in a 25-mL volumetric flask, add 5.0 mL of Internal standard solution, dilute with water to volume, and mix to obtain the Assay preparation.

Chromatographic system—The liquid chromatograph is equipped with a 225-nm detector and a 3.9-mm × 30-cm column that contains 10-µm packing L1. The flow rate is about 1.5 mL per minute. Chromatograph the Standard preparation, and record the peak responses as directed for Procedure: the resolution, R, between the levocarnitine and internal standard peaks is not less than 1.5; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure— Separately inject equal volumes (about 40 µL) of the Standard preparation and the Assay preparation into the chromatograph, record the chromatograms, and measure the responses for the major peaks. The relative retention times are about 0.56 for levocarnitine and 1.0 for p-aminobenzoic acid. Calculate the quantity, in mg, of levocarnitine (C₇H₁₅NO₃) in each mL of the Oral Solution taken by the formula:

$$250C / V(R_U / R_S)$$

in which C is the concentration, in mg per mL, of [USP Levocarnitine RS](#) in the Standard preparation; V is the volume, in mL, of Oral Solution taken; and R_U and R_S are the peak response ratios obtained from the Assay preparation and the Standard preparation, respectively.