

## Draft Guidance on Levocarnitine

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

**Active Ingredient:** Levocarnitine

**Dosage Form; Route:** Tablet; oral

**Recommended Studies:** Two studies

1. Type of study: Fasting  
Design: Single-dose, two-way crossover in vivo  
Strength: 330 mg  
Subjects: Healthy males, nonpregnant females, general population  
Additional comments: Measure baseline levocarnitine levels before dosing. The mean of the pre-dose levocarnitine levels should be used for the baseline adjustment of the post-dose levels. Baseline concentrations should be determined for each dosing period, and baseline corrections should be period-specific. If a negative plasma concentration value results after baseline correction, this should be set to 0 prior to calculating the baseline-corrected AUC. Analyze the pharmacokinetic parameters using both baseline-uncorrected and -corrected data.

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2. Type of study: Fed  
Design: Single-dose, two-way crossover in vivo  
Strength: 330 mg  
Subjects: Healthy males, nonpregnant females, general population  
Additional comments: Same as comments above

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**Analytes to measure (in appropriate biological fluid):** Levocarnitine in plasma

**Bioequivalence based on (90% CI):** Levocarnitine

**Waiver request of in vivo testing:** Not applicable

**Dissolution test method and sampling times:** The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods Web site, available to the public at the following location: <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Conduct comparative dissolution testing on 12 dosage units each of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).