

**Draft Guidance on Carglumic Acid**

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

**Active ingredient:** Carglumic Acid

**Form/Route:** Tablet/Oral

**Recommended studies:** 1 study

1. Type of study: Fasting  
Design: Single-dose, two-way crossover *in-vivo*  
Strength: 200 mg tablet\* (Dose 100 mg/kg)  
Subjects: Normal healthy males and non-pregnant females, general population.  
Additional Comments: 1. Females should not be pregnant or lactating, and if applicable, should practice abstention or contraception during the study.

\*Note: Because carglumic acid tablet is supplied as 200 mg tablets, the dose for each subject should be calculated by multiplying the subject's weight by 100 mg/kg and then rounding up to the next 200 mg dose. The tablets should not be swallowed whole or crushed. Disperse Carglumic Acid tablets in water immediately before use per the labeling instruction. Carglumic Acid tablets do not dissolve completely in water and undissolved particles of the tablet may remain in the mixing container. To ensure complete delivery of the dose, the mixing container should be rinsed with additional volumes of water and the contents swallowed immediately. The total volume of water should be 250 mL and the total calculated dose should be consumed. For data analysis, the dose administered should be included in the Analysis of Variance (ANOVA) statistical model. Dose normalization is not advised.

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**Analytes to measure (in appropriate biological fluid):** Carglumic acid

**Bioequivalence based on (90% CI):** Carglumic acid

**Waiver request of in-vivo testing:** N/A

**Dissolution test method and sampling times:**

Please note that a **Dissolution Methods Database** is available to the public at the OGD website at <http://www.fda.gov/cder/ogd/index.htm>. Please find the dissolution information for this product at this website. Please conduct comparative drug dissolution testing on 12 dosage units each of all strengths of the test and reference products. Specifications will be determined upon review of the application.