

Guidance on Acamprosate Calcium

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Active ingredient: Acamprosate Calcium

Form/Route: Delayed Release Tablet/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover *in-vivo*
Strength: 333 mg
Subjects: Normal healthy males and females, general population. Females should not be pregnant, and if applicable, should practice abstinence or contraception during the study.
Additional Comments:

2. Type of study: Fed
Design: Single-dose, two-way crossover *in-vivo*
Strength: 333 mg
Subjects: Normal healthy males and females, general population. Females should not be pregnant, and if applicable, should practice abstinence or contraception during the study.
Additional comments:

Analytes to measure: Acamprosate in plasma*

*Acamprosate exists completely dissociated in plasma. Therefore, BE measures may be reported in terms of acetylhomotaurine.

Bioequivalence based on (90% CI): Acamprosate*

*Please refer to the above section.

Waiver request of in-vivo testing: Not Applicable

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 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.