Contains Nonbinding Recommendations

Guidance on Lamotrigine

This guidance represents 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: Lamotrigine

Form/Route: Chewable Dispersible Tablet /Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover *in-vivo*
   Strength: Single-dose of 50 mg (2 x 25 mg)
   Subjects: Normal healthy males and females, general population
   Additional Comments:

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2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover *in-vivo*
   Strength: Single-dose of 50 mg (2 x 25 mg)
   Subjects: Normal healthy males and females, general population
   Additional comments:

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

* Please utilize a validated analytical method such as LC-MS/MS to reliably measure plasma lamotrigine concentrations. A lower limit of quantitation (LOQ) of 10 ng/mL is recommended to adequately characterize the pharmacokinetics at 50 mg study dose.

Bioequivalence based on (90% CI): Lamotrigine

Waiver request of in-vivo testing: 2 mg and 5 mg based on (i) acceptable bioequivalence studies on the 25 mg strength, (ii) proportional similarity of the formulations across all strengths, and (iii) acceptable in vitro dissolution testing of all strengths.

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 conduct comparative dissolution testing on 12 dosage units each of all strengths of the test and reference products.