

Draft Guidance on Lisdexamfetamine Dimesylate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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: Lisdexamfetamine dimesylate

Dosage Form; Route: Chewable tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 60 mg
Subjects: Adult males and non-pregnant, non-lactating females, general population
Additional comments: The tablets should be chewed and swallowed with water
2. Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 60 mg
Subjects: Adult males and non-pregnant, non-lactating females, general population
Additional comments: see above

Analytes to measure (in appropriate biological fluid): Lisdexamfetamine and dextroamphetamine (metabolite) in plasma

Please submit the metabolite data as supportive evidence of comparable therapeutic outcome. For the metabolite, the following data should be submitted: individual and mean concentrations, individual and mean pharmacokinetic parameters, and geometric means and ratios of means for AUC and C_{max} .

Bioequivalence based on (90% CI): Lisdexamfetamine

Waiver request of in vivo testing: 10 mg, 20 mg, 30 mg, 40 mg, and 50 mg based on (i) acceptable bioequivalence studies on the 60 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: 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 all strengths of the test and

reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).