Contains Nonbinding Recommendations

Draft Guidance on Benztropine Mesylate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Tablet; oral

Recommended Studies:

Benztropine mesylate tablets are Drug Efficacy Study Implementation (DESI) effective drug product without known bioequivalence problems. All three strengths of benztropine mesylate tablets are rated as "AA" in the current Orange Book. Therefore, in vivo bioequivalence testing is not recommended. The waiver of in vivo bioequivalence study requirements on this product may be requested under 21 CFR 320.22(c). Comparative dissolution testing on 12 dosage units of all strengths of the test and reference products shall be conducted to demonstrate the bioequivalence.

Waiver request of in-vivo testing: 0.5 mg, 1 mg, and 2 mg pursuant to 21 CFR 320.22(c)

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods website 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.

Since all strengths of benztropine mesylate tablets are scored, additional split tablet dissolution testing should be conducted. For additional information on the evaluation of scored tablets, refer to the FDA Guidance on "Tablet Scoring: Nomenclature, Labeling, and Data for Evaluation."