Contains Nonbinding Recommendations

Draft Guidance on Flavoxate Hydrochloride

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in vivo
   Strength: 100 mg
   Subjects: Males and non-pregnant, non-lactating females, general population
   Additional comments: None

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2. Type of study: Fed
   Design: Single-dose, two-way crossover in vivo
   Strength: 100 mg
   Subjects: Males and non-pregnant, non-lactating females, general population
   Additional comments: None

Analytes to measure (in appropriate biological fluid): Flavoxate and the metabolite, 3-methyl-flavone-8-carboxylic acid in plasma

Bioequivalence based on (90% CI): Flavoxate or the metabolite, 3 methyl-flavone-8-carboxylic acid. If flavoxate can be reliably measured, a confidence interval approach for bioequivalence determination should be used for flavoxate. If flavoxate cannot be reliably measured, a confidence interval approach for bioequivalence determination should be used for 3-methyl-flavone-8-carboxylic acid.

Waiver request of in vivo testing: Not applicable

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 the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.