Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Tafamidis

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Capsule; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 61 mg
   Subjects: Males and non-pregnant, non-lactating females, general population
   Additional comments: Ensure an adequate washout period between treatments in the crossover study due to the long elimination half-life of tafamidis. Alternatively, a parallel study design may be considered. The capsules should be swallowed whole and not crushed or cut.

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2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 61 mg
   Subjects: Males and non-pregnant, non-lactating females, general population
   Additional comments: See comments above.

Analyte to measure: Tafamidis in plasma

Bioequivalence based on (90% CI): Tafamidis

Waiver request of in vivo testing: Not applicable

Dissolution test method and sampling times: The dissolution information for this drug product can be found in the FDA's Dissolution Methods database, http://www.accessdata.fda.gov/scripts/cder/dissolution/. Conduct comparative dissolution testing on 12 dosage units for each of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.