Contains Nonbinding Recommendations

Draft Guidance on Balsalazide Disodium

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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: Balsalazide Disodium

Form/Route: Capsule/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover *in-vivo*
   Strength: 2250 mg dose (3 x 750 mg)
   Subjects: Normal healthy males and females, general population. Females should not be pregnant, and if applicable, should practice abstention or contraception during the study.
   Additional comments:

---

2. Type of study: Fed
   Design: Single-dose, two-way crossover *in-vivo*
   Strength: 2250 mg dose (3 x 750 mg)
   Subjects: Normal healthy males and females, general population
   Additional comments: Please see comment above.

Analytes to measure (in appropriate biological fluid): Balsalazide and Mesalamine in plasma

Bioequivalence based on (90% CI): Balsalazide and Mesalamine

Waiver request of in-vivo testing: Not Applicable

In vitro dissolution testing under the following conditions should be submitted to support documentation of bioequivalence:

Apparatus and rotation speed:	USP Apparatus 1 (basket), at 100 rpm
Medium:	(1) 0.1N HCl (2) pH 4.5 buffer (3) pH 6.8 buffer (4) pH 7.4 buffer
Volume:	900 mL
Temperature:	37ºC
Sample times:	5, 10, 15, 20, 30, 45 and 60 minutes and until at least 80% of the labeled content is dissolved.

Dissolution testing for stability and quality control:

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. Please 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 application.