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: 37°C
- 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.

Recommended Jan 2008