Active ingredient: Olsalazine Sodium

Form/Route: Capsule/Oral

Recommended studies: 1 study

Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in-vivo
Strength: 250 mg
Subjects: Normal healthy males and females, general population
Additional Comments: Please use the lowest single dose possible to obtain accurate pharmacokinetic parameters for both olsalazine and mesalamine. Please enroll enough subjects to achieve adequate statistical power to demonstrate bioequivalence to the RLD. A pilot study may be necessary to assist in the determination of the appropriate number of subjects to enroll in the pivotal study. The number of subjects should be sufficient to allow for dropouts. You may also refer to Appendix C of the Guidance for Industry, “Statistical Approaches to Establishing Bioequivalence” at http://www.fda.gov/cder/ guidance/index.htm.

Analytes to measure (in appropriate biological fluid): Olsalazine and mesalamine in plasma.

Bioequivalence based on (90% CI): Olsalazine and mesalamine

Waiver request of in-vivo testing: Not applicable

Dissolution test method and sampling times:

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. In addition, please perform dissolution testing over a range of pH values comparing the test and reference products. Varying pH conditions should be studied to approximate the pH conditions that olsalazine sodium capsules will be subjected to in the GI tract. Therefore, the following pH conditions should be used using 12 dosage units of the test and reference products:

| Apparatus: | USP Apparatus I (basket) |
| Speed: | 100 rpm |
| Medium: | 0.1N HCl; pH 4.5 buffer; pH 6.8 buffer |
| Volume: | 900 mL |
| Sampling Times: | 5, 10, 15, 20, 30, 45, and 60 minutes and until at least 80% of the labeled content is dissolved. |

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