Contains Nonbinding Recommendations

Guidance on Olsalazine Sodium

This guidance represents 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: 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.