Contains Nonbinding Recommendations

Draft Guidance on Mesalamine

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

Form/Route: Enema /Rectal

Recommended studies: 1 study

The following study is recommended to establish bioequivalence of mesalamine rectal enema provided that the test product is qualitatively (Q1) and quantitatively (Q2) the same as the RLD:

Type of study: Fasting
Design: Single-dose, two-way crossover *in-vivo* or replicate design
Strength: 4 Gm/ 60 ml
Subjects: Normal healthy males and females, general population
Additional Comments: The proposed generic and RLD formulations should have comparable particle size.

Analytes to measure (in appropriate biological fluid: Mesalamine (5-ASA) in plasma.

Bioequivalence based on (90% CI): Mesalamine (5-ASA)

Waiver request of in-vivo testing: Not Applicable

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

Please conduct comparative dissolution testing on 12 dosage units of the test and reference products using 900 mL of the following media: 0.1N HCl, and buffers at pH 4.5, pH 6.8 and pH 7.2 using apparatus 2 (paddle) at 25 and 50 rpm. Please ensure that the dissolution method is adequate to distinguish mesalamine dissolved in dissolution media from drug particles. You may modify the filtration method in the dissolution testing, if necessary.

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.