

Draft Guidance on Aminosalicyclic Acid

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

Form/Route: Delayed Release Granules/Oral

Recommended studies: 3 studies

1. Type of study: Fasting
Design: Single-dose, two-way, crossover *in-vivo*
Strength: 4 gm
Subjects: Normal healthy males and females, general population
Additional Comments: Females should not be pregnant or lactating, and if applicable, should practice abstinence or contraception during the study. The test and reference products should be administered by suspending the granules in orange or tomato juice. The pH of the food in which the granules are suspended should be less than 5. Care should be taken during the administration of these granules to protect the acid-resistant coating by maintaining the granules in an acidic environment during administration. The product should be stored in a refrigerator or freezer, but may be stored at room temperature for short periods of time. Avoid exposure of the drug to moisture, heat or light.

2. Type of study: Fed
Design: Single-dose, two-way, crossover *in-vivo*
Strength: 4 gm
Subjects: Normal healthy males and females, general population
Additional comments: Please see comments above.

3. Type of study: Fasting sprinkle-in-applesauce
Design: Single-dose, two-way, crossover *in-vivo*
Strength: 4 gm
Subjects: Normal healthy males and females, general population
Additional comments: Please administer the dose after sprinkling the entire contents of the capsule on a teaspoonful of applesauce in accordance with the approved labeling of the RLD. Please see comments above.

Analytes to measure: Aminosalicyclic acid in serum

Bioequivalence based on (90% CI): Aminosalicyclic acid

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.