

## **Draft Guidance on Methylalntrexone Bromide**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

**Active Ingredient:** Methylalntrexone bromide

**Dosage Form; Route:** Tablet; oral

**Recommended Studies:** One study

1. Type of study: Fasting

Design: Single-dose, two-way crossover in-vivo

Strength: 150 mg (recommended dose 450 mg (3 x 150 mg tablets))

Subjects: Healthy males and non-pregnant, non-lactating females, general population

Additional Comments: None

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**Analytes to measure (in appropriate biological fluid):** methylalntrexone

**Bioequivalence based on (90% CI):** methylalntrexone

**Waiver request of in-vivo testing:** Not applicable

**Dissolution test method and sampling times:** The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods web site, available to the public at the following location: <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. 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 abbreviated new drug application (ANDA).