

Draft Guidance on Metaxalone

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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: Metaxalone

Dosage Form; Route: Tablets; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 800 mg
Subjects: Males and non-pregnant, non-lactating females, general population
Additional comments: Applicants may consider using a reference-scaled average bioequivalence approach for metaxalone. If using this approach, provide evidence, from the bioequivalence study, of high variability in the bioequivalence parameters of AUC and/or C_{max} (i.e., within-subject variability $\geq 30\%$). Refer to the Progesterone Capsule Guidance for additional information regarding method for statistical analysis.

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2. Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 800 mg
Subjects: Males and non-pregnant, non-lactating females, general population
Additional comments: See comment above.
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Analytes to measure (in appropriate biological fluid): Metaxalone in plasma

Bioequivalence based on (90% CI): Metaxalone

Waiver request of in vivo testing: 400 mg based on (i) acceptable bioequivalence studies on the 800 mg strength, (ii) proportional similarity of the formulations across all strengths, and (iii) acceptable in vitro dissolution testing of all strengths.

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods website 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).