

Draft Guidance on Metaxalone

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

Form/Route: Tablet/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover *in-vivo*
Strength: 800 mg
Subjects: Normal healthy males and females, general population
Additional Comments:

2. Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover *in-vivo*
Strength: 800 mg
Subjects: Normal healthy males and females, general population
Additional comments:

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.*

* Please note that Metaxalone Tablets, 400 mg, have been discontinued from the market. If you would like to market the 400 mg strength, please submit a Citizen Petition pursuant to 21 C.F.R. 314.122, requesting that the FDA determine whether this strength was discontinued due to safety and/or effectiveness reasons. Please follow the Citizen Petition format outlined in 21 CFR 10.20 and 10.30.

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.