

Guidance on Quetiapine Fumarate

This guidance represents 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: Quetiapine Fumarate

Form/Route: Tablet /Oral

Recommended studies: 3 studies

1. Type of study: Fasting
Design: Single-dose, in-vivo
Strength: 25 mg
Subjects: Normal healthy males and females, general population
Additional Comments: Please include careful safety precautions in your protocols, including adequate monitoring of vital signs and adverse events, stopping criteria in the event of an unacceptable degree of hypotension or tachycardia, and appropriate evaluation and management of adverse events. Please assure that the investigator(s) will be vigilant in recognizing and managing any unacceptable clinical or laboratory findings. It is recommended that a study protocol be submitted for review before initiating a bioequivalence study for this product.

2. Type of study: Fed
Design: Single-dose, in-vivo
Strength: 25 mg
Subjects: Normal healthy males and females, general population
Additional comments: Please see comments above.

3. Type of study and design: Steady-state, in-vivo
Strength: 300 mg
Subjects: Schizophrenic patients already receiving quetiapine in a stable regimen.
Additional comments: Please see comments above.

Analytes to measure: Quetiapine in plasma.

Bioequivalence based on (90% CI): Quetiapine

Waiver request of in-vivo testing: 50 mg, 100 mg, 150 mg, 200 mg, and 400 mg based on (i) acceptable bioequivalence studies on the 25 mg and 300 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:

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.