Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Quetiapine Fumarate

October 2024

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

Active Ingredient:	Quetiapine fumarate
Dosage Form:	Tablet
Route:	Oral
Strengths:	EQ 25 mg Base, EQ 50 mg Base, EQ 100 mg Base, EQ 150 mg Base, EQ 200 mg Base, EQ 300 mg Base, EQ 400 mg Base
Recommended Studies:	Two in vivo bioequivalence studies with pharmacokinetic endpoints

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 25 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Include careful safety precautions in 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. Assure that the investigator(s) will be vigilant in recognizing and managing any unacceptable clinical or laboratory findings.

2. Type of study: Steady-state
   Design: In vivo
   Strength: EQ 300 mg Base
   Subjects: Schizophrenic patients already receiving quetiapine in a stable regimen.
   Additional comments: Exclude patients who require dosage modification or with expected changes in concomitant medications that may potentially affect the pharmacokinetics of quetiapine during the study. Implement safety precautions and

monitoring during treatment as recommended in the labeling.

Analyte to measure: Quetiapine in plasma

Bioequivalence based on (90% CI): Quetiapine

Waiver request of in vivo testing: EQ 50 mg Base, EQ 100 mg Base, EQ 150 mg Base, EQ 200 mg Base, and EQ 400 mg Base strengths, based on (i) acceptable bioequivalence studies on the EQ 25 mg Base and EQ 300 mg Base strengths, (ii) acceptable in vitro dissolution testing of all strengths, and (iii) proportional similarity of the formulations across all strengths

Dissolution test method and sampling times: The dissolution information for this drug product can be found in the FDA's Dissolution Methods database, http://www.accessdata.fda.gov/scripts/cder/dissolution/. Conduct comparative dissolution testing on 12 dosage units for each of all strengths of the test product and reference listed drug (RLD).[1] Specifications will be determined upon review of the abbreviated new drug application.

Document History: Recommended May 2007; Finalized May 2008; Revised October 2024

Unique Agency Identifier: PSG_020639

[1] If the RLD is not available, refer to the most recent version of the FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions*.