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Draft Guidance on Azithromycin

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

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Active Ingredient: Azithromycin

Dosage Form: Tablet

Route: Oral

Strengths: EQ 250 mg Base, EQ 500 mg Base, EQ 600 mg Base

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 600 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: None

Analyte to measure: Azithromycin

Bioequivalence based on (90% CI): Azithromycin

Waiver request of in vivo testing*: EQ 250 mg Base and EQ 500 mg Base strengths based on (i) acceptable bioequivalence study on the EQ 600 mg Base strength, (ii) acceptable in vitro dissolution testing of all strengths, and (iii) proportionally similarity of the formulation across all strengths

* Since azithromycin tablets, 250 mg, 500 mg, and 600 mg, are the subject of three separate new drug applications, three separate abbreviated new drug applications (ANDA) must be submitted. Applicants may request a waiver of in vivo bioequivalence testing of the 250 mg and the 500 mg strengths if the criteria are met. In addition, cross-reference the in vivo bioequivalence studies conducted on the higher strength along with the waiver request. Refer to the most recent version of the FDA guidance for industry on *Variations in Drug Products that May Be Included in a Single ANDA.*[a]

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.

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[a] For the most recent version of a guidance, check the FDA guidance website at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[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*.