

**Draft Guidance on Hydrochlorothiazide; Olmesartan Medoxomil**

**October 2024**

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**Active Ingredients:** Hydrochlorothiazide; Olmesartan medoxomil

**Dosage Form:** Tablet

**Route:** Oral

**Strengths:** 12.5 mg; 20 mg, 12.5 mg; 40 mg, 25 mg; 40 mg

**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: 25 mg; 40 mg  
Subjects: Healthy males and non-pregnant, non-lactating females  
Additional comments: Females of reproductive potential should use effective contraception during the study.

**Analytes to measure:** Hydrochlorothiazide and olmesartan in plasma

**Bioequivalence based on (90% CI):** Hydrochlorothiazide and olmesartan

**Waiver request of in vivo testing:** 12.5 mg; 40 mg and 12.5 mg; 20 mg strengths, based on (i) acceptable bioequivalence study on the 25 mg; 40 mg strength, (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).<sup>1</sup> Specifications will be determined upon review of the abbreviated new drug application.

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

**Unique Agency Identifier:** PSG\_021532

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<sup>1</sup> 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*.