*Contains Nonbinding Recommendations*

*Draft – Not for Implementation*

**Draft Guidance on Losartan Potassium**

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

**Dosage Form:** Tablet

**Route:** Oral

**Strengths:** 25 mg, 50 mg, 100 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: 100 mg
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Applicants may consider using a reference-scaled average bioequivalence approach for losartan potassium. If using this approach, provide evidence of high variability in the pharmacokinetic parameters (i.e., within-subject variability ≥30%) for the reference product. For detailed information on this approach, refer to the most recent version of the FDA guidance for industry on *Bioequivalence Studies With Pharmacokinetic Endpoints for Drugs Submitted Under an abbreviated new drug application (ANDA).*[a]

**Analyte to measure:** Losartan in plasma

**Bioequivalence based on (90% CI):** Losartan

**Waiver request of in vivo testing:** 25 mg and 50 mg strengths based on (i) an acceptable bioequivalence study on the 100 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).[1] Specifications will be determined upon review of the ANDA.

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**Unique Agency Identifier:** PSG_020386

[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*.