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Draft Guidance on Teriflunomide

October 2024

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Active Ingredient: Teriflunomide

Dosage Form: Tablet

Route: Oral

Strengths: 7 mg, 14 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: 14 mg
   Subjects: Healthy males
   Additional comments: Exclude male subjects wishing to father a child during the study. Ensure an adequate washout period between treatments in the crossover study due to the long elimination half-life of teriflunomide. Alternatively, a parallel study design may be considered.

Analyte to measure: Teriflunomide in plasma

Bioequivalence based on (90% CI): Teriflunomide

Waiver request of in vivo testing: 7 mg strength based on (i) acceptable bioequivalence study on the 14 mg strength, (ii) acceptable in vitro dissolution testing of both strengths, and (iii) proportional similarity of the formulations between both 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 both 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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[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.*