Draft Guidance on Naproxen Sodium

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

Active ingredient: Naproxen Sodium

Form/Route: Extended Release Tablet/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in-vivo
   Strength: 750 mg
   Subjects: Healthy males and nonpregnant females, general population.
   Additional Comments: This drug product is designed to provide both a quick onset and prolonged action. Please ensure that the Tmax (time to peak plasma naproxen concentrations) is comparable between the test and reference products.

2. Type of study: Fed
   Design: Single-dose, two-way crossover in-vivo
   Strength: 750 mg
   Subjects: Healthy males and nonpregnant females, general population.
   Additional Comments: See comment above.

Analytes to measure (in appropriate biological fluid): Naproxen in plasma

Bioequivalence based on (90% CI): Naproxen

Waiver request of in-vivo testing: 375 mg and 500 mg based on (i) acceptable bioequivalence studies on the 750 mg strength, (ii) proportional similarity in the formulations of all strengths, and (iii) acceptable in vitro dissolution testing of all strengths.

Dissolution test method and sampling times:

Please note that a Dissolution Methods Database is available to the public at the OGD website at http://www.accessdata.fda.gov/scripts/cder/dissolution/. Please find the dissolution information for this product at this website. Please conduct comparative dissolution testing on 12 dosage units each of all strengths of the test and reference products. Specifications will be determined upon review of the application.

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