Contains Nonbinding Recommendations

Guidance on Dapsone

This guidance represents 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.

Active Ingredient: Dapsone

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in vivo
   Strength: 100 mg
   Subjects: Healthy males and nonpregnant females, general population.
   Additional Comments: For long half-life drug products that demonstrate low intrasubject variability in distribution and clearance, an AUC truncated at 72 hours may be used in place of AUC_{0-t} or $AUC_{0-\infty}$. A parallel study design is also acceptable.

---

2. Type of study: Fed
   Design: Single-dose, two-way crossover in vivo
   Strength: 100 mg
   Subjects: Healthy males and nonpregnant females, general population.
   Additional Comments: See comments above.

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

Bioequivalence based on (90% CI): Dapsone

Waiver request of in-vivo testing: 25 mg based on (i) acceptable bioequivalence studies on the 100 mg strength (ii) proportional similarity of the formulations across all strengths, and (iii) acceptable in vitro dissolution testing of all strengths.

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods website, available to the public at the following location: http://www.accessdata.fda.gov/scripts/cder/dissolution/. 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 abbreviated new drug application (ANDA).