Contains Nonbinding Recommendations

Draft Guidance on Ibuprofen

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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: Ibuprofen

Form/Route: Suspension/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way, crossover *in-vivo*
   Strength: 100 mg/5 ml
   Males and females, general population
   Additional Comments: Please conduct study on McNeils Ped's Motrin® (Ibuprofen for Oral Suspension, (100 mg/ 5 ml, Rx).

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2. Type of study: Fed
   Design: Single-dose, two-way, crossover *in-vivo*
   Strength: 100 mg/5 ml
   Subjects: Normal healthy males and females, general population
   Additional comments: Please see comment above.

Analytes to measure: Ibuprofen in plasma

Bioequivalence based on (90% CI): Ibuprofen

Waiver request of in-vivo testing: McNeils Ped's Motrin® (Ibuprofen for Oral Suspension, 100 mg/ 5 ml, Rx) may be referenced to support a request for a waiver for McNeils Children's Motrin® (Ibuprofen for Oral Suspension, 100 mg/ 5 ml, OTC) based on (i) acceptable bioequivalence studies on the McNeils Ped's Motrin®, (ii) acceptable dissolution testing across all strengths, and (iii) proportional similarity in the formulations across 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.fda.gov/cder/ogd/index.htm. Please find the dissolution information for this product at this website. Please note that a dosage unit is based on the labeled concentration of the suspension product. Please use the dosage unit (5 ml). A total of 12 units from 12 different bottles should be used. Specifications will be determined upon review of the application.