Guidance on Nevirapine

Active ingredient: Nevirapine

Form/Route: Suspension /Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, one-period parallel *in-vivo*
   Strength: 50 mg/5mL
   Subjects: Normal healthy males and females, general population
   Additional Comments: Due to safety concerns of sever life threatening skin reactions and hepatotoxicity, single dose parallel study designs in normal healthy subjects are recommended.

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2. Type of study: Fed
   Design: Single-dose, one-period parallel *in-vivo*
   Strength: 50 mg/5mL
   Subjects: Normal healthy males and females, general population
   Additional comments: Please see comments above.

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

Bioequivalence based on (90% CI): Nevirapine

Waiver request of in-vivo testing: Not Applicable

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 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.