Draft Guidance on Secnidazole

Active Ingredient: Secnidazole

Dosage Form; Route: Granules; oral

Recommended studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover \textit{in-vivo}
   Strength: 2 GM/ Packet
   Subjects: Healthy non-pregnant, non-lactating females.
   Additional Comment: None

2. Type of study: Fed
   Design: Single-dose, two-way crossover \textit{in-vivo}
   Strength: 2 GM/ Packet
   Subjects: Healthy non-pregnant, non-lactating females.
   Additional comment: None

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

Bioequivalence based on (90\% CI): Secnidazole

Waiver request of in-vivo testing: N/A

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: \url{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).