Active Ingredient: Lesinurad

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in vivo
   Strength: 200 mg
   Subjects: Healthy males and nonpregnant females, general population.
   Additional Comments: Subjects should remain well hydrated throughout the study (e.g., 2 liters [68 oz] of liquid per day).

2. Type of study: Fed
   Design: Single-dose, two-way crossover in vivo
   Strength: 200 mg
   Subjects: Healthy males and nonpregnant females, general population.
   Additional Comments: Same as above.

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

Bioequivalence based on (90% CI): Lesinurad

Waiver request of in vivo testing: Not Applicable

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).