Draft Guidance on Trientine Hydrochloride

Active ingredient: Trientine Hydrochloride

Form/Route: Capsules/Oral

Recommended studies: 1 study

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in vivo
   Strength: 250 mg
   Subjects: Healthy males and nonpregnant females, general population.
   Additional Comments: Females should practice abstention or contraception during the study.

Analytes to measure (in appropriate biological fluid): Trientine and its metabolite, N₁-acetyltetriethylenetetramine, in plasma.

Please submit the metabolite data as supportive evidence of comparable therapeutic outcome. For the metabolite, the following data should be submitted: individual and mean concentrations, individual and mean pharmacokinetic parameters, and geometric means and ratios of means for AUC and Cmax.

Bioequivalence based on (90% CI): Trientine

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.accessdata.fda.gov/scripts/cder/dissolution/. 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.