Contains Nonbinding Recommendations

Draft Guidance on Busulfan

Active ingredient: Busulfan

Form/Route: Tablets/Oral

Recommended studies: 1 study

Type of study: Fasting
Design: Single-dose, two-way, crossover *in-vivo*
Strength: 2 mg (dose 2 mg)
Subjects: Males and nonpregnant female patients who are on a regimen of oral busulfan tablets.
Additional comments: Submission of an Investigational New Drug Application (IND) is required prior to conducting a bioequivalence study for a cytotoxic drug product such as busulfan (See 21 C.F.R § 320.31).

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

Bioequivalence based on (90% CI): Busulfan

Waiver request of *in-vivo* testing: Not Applicable

Dissolution test method and sampling times:

Please note that **Dissolution Method 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.