

Draft Guidance on Busulfan

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

Active ingredient: Busulfan

Form/Route: Tablets/Oral

Recommended studies: 1study

Type of study: Fasting

Design: Single-dose, two-way, crossover *in-vivo*

Strength: 2 mg (dose 2 mg)

Subjects: Patients who are on a regimen of oral busulfan tablets or have previously been determined to be candidates for 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.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.