

Contains Nonbinding Recommendations

Draft Guidance on Indomethacin

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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: Indomethacin

Form/Route: Extended Release Capsule/Oral

Recommended studies: 1 study

1. Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover, *in-vivo*
Strength: 75 mg
Subjects: Healthy males and nonpregnant females, general population
Addition Comments: Due to safety concerns, a fasting study is not recommended.

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

Bioequivalence based on (90% CI): Indomethacin

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.

In addition to the method above, for modified release products, dissolution profiles on 12 dosage units each of test and reference products generated using USP Apparatus I at 100 rpm and/or Apparatus II at 50 rpm in at least three dissolution media (pH 1.2, 4.5 and 6.8 buffer) should be submitted in the application. Agitation speeds may have to be increased if appropriate. It is acceptable to add a small amount of surfactant, if necessary. Please include early sampling times of 1, 2, and 4 hours and continue every 2 hours until at least 80% of the drug is released, to provide assurance against premature release of drug (dose dumping) from the formulation. Specifications will be determined upon review of the data submitted in the application.