

Draft Guidance on Nabilone

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

Form/Route: Capsule/Oral

Recommended studies: 2 studies

Type of study: Fasting

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

Strength: 1 mg

Subjects: Cancer patients receiving chemotherapy treatment and who have failed to respond adequately to conventional antiemetic treatments.

Additional Comments: Patients with a history of substance abuse, including alcohol abuse or dependence and marijuana use, should be excluded from the study. This drug may induce psychotomimetic reactions (e.g. hallucinations, disorientation and disordered thinking as well as other CNS reactions such as, sedation, ataxia, and depression) that can persist for 48 to 72 hours following cessation of treatment. It is recommended that patients be closely monitored in the study for at least 72 hours.

Analytes to measure: Nabilone in plasma

Bioequivalence based on (90% CI): Nabilone

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.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.