Contains Nonbinding Recommendations

Draft Guidance on Ondansetron

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

Form/Route: Film/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in vivo
   Strength: 8 mg
   Subjects: Healthy males and females, general population.
   Additional Comments: The drug product should be placed on the tongue until it dissolves and should not be administered with water.

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2. Type of study: Fed
   Design: Single-dose, two-way crossover in vivo
   Strength: 8 mg
   Subjects: Healthy males and females, general population.
   Additional Comments: The drug product should be placed on the tongue until it dissolves and should not be administered with water. Please refer to the Amantadine Hydrochloride Tablet Draft Guidance for additional information regarding fed studies.

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

Bioequivalence based on (90% CI): Ondansetron

Waiver request of in-vivo testing: 4 mg based on (i) acceptable bioequivalence studies on the 8 mg strength, (ii) acceptable in vitro dissolution testing of all strengths, and (iii) proportional similarity of the formulations across all strengths.

Please refer to the Mirtazapine Tablet Draft Guidance for additional information regarding waivers of in vivo testing.

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.