Contains Nonbinding Recommendations

Guidance on Atomoxetine Hydrochloride

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

Form/Route: Capsules/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover *in-vivo*
   Strength: 60 mg
   Subjects: Normal healthy males and females, general population
   Additional Comments: 60 mg is studied because higher doses may cause unacceptable side-effects in normal healthy subjects

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2. Type of study: Fed
   Design: Single-dose, two-way crossover *in-vivo*
   Strength: 60 mg
   Subjects: Normal healthy males and females, general population
   Additional comments: Please see comment above.

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

Bioequivalence based on (90% CI): Atomoxetine

Waiver request of in-vivo testing: 5**, 10, 18, 25, 40, 80 and 100 mg based on (i) acceptable bioequivalence studies on the 60 mg strength, (ii) proportionally similar across all strengths, and (iii) acceptable in vitro dissolution testing of all strengths.

****** The 5 mg strength of STRATTERA™ is currently not marketed. If a firm is interested in seeking approval for this strength, please submit a citizen petition requesting the U.S. Food and Drug Administration (FDA) make a determination that this particular strength was not withdrawn for reasons of safety or effectiveness, or check the Federal Register for a previously submitted citizen petition. Submission of the citizen petition to the FDA should be done prior to an ANDA submission.

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.