

Contains Nonbinding Recommendations

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Draft Guidance on Atomoxetine Hydrochloride

October 2024

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Active Ingredient:	Atomoxetine hydrochloride
Dosage Form:	Capsule
Route:	Oral
Strengths:	EQ 5 mg Base, EQ 10 mg Base, EQ 18 mg Base, EQ 25 mg Base, EQ 40 mg Base, EQ 60 mg Base, EQ 80 mg Base, EQ 100 mg Base
Recommended Study:	One in vivo bioequivalence study with pharmacokinetic endpoints
1.	Type of study: Fasting Design: Single-dose, two-treatment, two-period crossover in vivo Strength: EQ 60 mg Base Subjects: Healthy males and non-pregnant, non-lactating females Additional comments: None

Analyte to measure: Atomoxetine in plasma

Bioequivalence based on (90% CI): Atomoxetine

Waiver request of in vivo testing: EQ 5 mg Base, EQ 10 mg Base, EQ 18 mg Base, EQ 25 mg Base, EQ 40 mg Base, EQ 80 mg Base, and EQ 100 mg Base strengths, based on (i) an acceptable bioequivalence study on the EQ 60 mg Base strength, (ii) acceptable in vitro dissolution testing of all strengths, and (iii) proportional similarity of the formulations across all strengths

Dissolution test method and sampling times: The dissolution information for this drug product can be found in the FDA’s Dissolution Methods database, <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Conduct comparative dissolution testing on 12 dosage units for each of all strengths of the test product and reference listed drug (RLD).¹ Specifications will be determined upon review of the ANDA.

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¹ If the RLD is not available, refer to the most recent version of the FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions*.