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Draft Guidance on Escitalopram Oxalate

December 2025

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Active Ingredient:	Escitalopram oxalate
Dosage Form:	Tablet, orally disintegrating[1]
Route:	Oral
Strengths:	EQ 5 mg Base[1], EQ 10 mg Base[1], EQ 15 mg Base[1], EQ 20 mg Base
Recommended Studies:	Two options: (1) two in vivo bioequivalence studies with pharmacokinetic endpoints using the designated reference standard (RS) for escitalopram oxalate tablets, or (2) one in vivo bioequivalence study with pharmacokinetic endpoints using the designated RS for escitalopram oxalate orally disintegrating tablets (ODTs)

I. Option 1: Two in vivo bioequivalence studies with pharmacokinetic endpoints using the designated RS for escitalopram oxalate tablets

1. Type of study: Fasting
   Design: Single-dose, three-treatment, three-period, crossover in vivo
   Strength: EQ 20 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Conduct the study by testing one escitalopram oxalate ODT of the test drug product, administered with and without water, compared to one escitalopram oxalate tablet of the RS with water.

[1] New dosage form and strengths identified are the subject of an approved suitability petition (FDA-2024-P-1870).

2. Type of study: Fed
Design: Single-dose, two-treatment, two-period, crossover in vivo
Strength: EQ 20 mg Base
Subjects: Healthy males and non-pregnant, non-lactating females
Additional comments: Conduct the study by testing one escitalopram oxalate ODT of the test drug product administered without water, compared to one escitalopram oxalate tablet of the RS with water.

II. Option 2: One in vivo bioequivalence study with pharmacokinetic endpoints using the designated RS for escitalopram oxalate ODT[2]

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: EQ 20 mg Base
Subjects: Healthy males and non-pregnant, non-lactating females
Additional comments: Conduct the study by testing one escitalopram oxalate ODT of the test drug product, administered without water compared to one escitalopram oxalate ODT of the RS without water.

Analyte to measure: Escitalopram in plasma

Bioequivalence based on (90% CI): Escitalopram

Waiver request of in vivo testing: EQ 5 mg Base, EQ 10 mg Base, and EQ 15 mg Base strengths based on (i) acceptable bioequivalence studies on the EQ 20 mg Base strength, (ii) acceptable in vitro dissolution testing of all the 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 the RS. Specifications will be determined upon review of the abbreviated new drug application.

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Unique Agency Identifier: PSG_021323-ODT

[2] This option can be used when a petitioned ANDA for escitalopram oxalate ODT is approved and designated as the RS.