Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Acetaminophen; Butalbital

October 2025

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Active Ingredients: Acetaminophen; Butalbital

Dosage Form: Capsule

Route: Oral

Strength: 300 mg; 50 mg[1]

Recommended Study: Request for waiver of in vivo bioequivalence study

Acetaminophen; butalbital capsules are a DESI[2] effective drug for which there are no known or suspected bioequivalence problems, and as such is rated "AA" in the FDA/CDER's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book").

Analyte to measure: Not applicable

Bioequivalence based on (90% CI): Not applicable

Waiver request of in vivo testing: 300 mg; 50 mg strength pursuant to 21 CFR 320.22(c) provided that the in vitro dissolution profile of the proposed products is comparable to that of the reference listed drug (RLD)[3]

[1] Strength is the subject of an approved suitability petition (FDA-2011-P-0167).
[2] Drug Efficacy Study Implementation
[3] 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.*

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 each of all strengths of the test product and RLD. Specifications will be determined upon review of the abbreviated new drug application.

Document History: Recommended March 2010; Revised October 2025

Unique Agency Identifier: PSG_088831