Active ingredient: Aspirin; Butalbital; Caffeine

Form/Route: Tablet/Oral

Recommended studies:

Aspirin; Butalbital; Caffeine Tablets is a DESI\(^1\) effective drug product 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”).

Analytes to measure (in appropriate biological fluid): Not Applicable

Bioequivalence based on (90% CI): Not Applicable

Waiver request of in-vivo testing: 325 mg/50 mg/40 mg pursuant to 21 CFR 320.22(c) provided that the in-vitro dissolution profiles of the proposed product are comparable to those of the reference product.

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.

\(^{1}\) Drug Efficacy Study Implementation