Active Ingredient: Cyproheptadine hydrochloride

Dosage Form; Route: Tablet; oral

Recommended studies: Cyproheptadine hydrochloride is a Drug Efficacy Study Implementation (DESI)-effective drug for which there are no known or suspected bioequivalence (BE) problems, and as such is rated “AA” in FDA/CDER’s Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”).

Analytes to measure (in appropriate biological fluid): Not applicable (N/A)

Bioequivalence based on (90% CI): N/A

Waiver request of in vivo testing: 4 mg tablet, pursuant to 21 CFR 320.22 (c)

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods Web site available to the public at the following location: http://www.accessdata.fda.gov/scripts/cder/dissolution/. Conduct comparative dissolution testing on 12 dosage units of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).