Draft Guidance on Glycopyrrolate

Active ingredient: Glycopyrrolate

Form/Route: Tablets/Oral

Recommended studies: No in-vivo bioequivalence studies

Glycopyrrolate Tablet is a Drug Efficacy Study Implementation (DESI) - effective drug for which there are no known or suspected bioequivalence problems, and as such is rated “AA” in 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: 1 mg and 2 mg strengths of the test drug products, based on acceptable formulation data and in vitro dissolution testing under the criteria set forth in 21 CFR 320.22 (c).

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.