Contains Nonbinding Recommendations

Draft Guidance on Methscopolamine Bromide

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

Active Ingredient: Methscopolamine bromide

Dosage Form; Route: Tablet; oral

Recommended Studies: Methscopolamine Bromide Tablet is a DESI[1] 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: 2.5 mg and 5.0 mg pursuant to 21 CFR 320.22 (c) provided the in-vitro dissolution profiles of your product are comparable to those of the reference product.

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 each of all strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).

[1] Drug Efficacy Study Implementation