Contains Nonbinding Recommendations

Draft Guidance on Oxybutynin

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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:	Oxybutynin
Dosage Form; Route:	Gel, metered; transdermal
Recommended Study:	One study
Type of study:	In vivo bioequivalence study
Design:	Single-dose, two-treatment, two-period crossover
Strength:	3%
Subjects:	Healthy males and nonpregnant females, general population
Additional comments:	Three actuations of gel, 28 mg oxybutynin/actuation (total 84 mg of oxybutynin in 2.8 g of gel) should be dosed as recommended in the reference listed drug (RLD) label to evenly cover the same surface area of skin for the test and reference products. Application of the gel should be randomized to one side of the abdomen for the RLD in one study period and to the contralateral side of the abdomen for the test product in the other study period.

Analyte to measure (in appropriate biological fluid):	Oxybutynin in plasma (achiral assay)
Bioequivalence based on (90% CI):	Oxybutynin
Waiver request of in vivo testing:	Not applicable
Dissolution test method and sampling times:	Not applicable