

Draft Guidance on Testosterone

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

Active ingredient: Testosterone

Form/Route: Solution, Metered/Transdermal

Waiver option:

- a. To qualify for a waiver of the in vivo bioequivalence study requirement under 21 CFR 320.22(b)(3), generic versions of Testosterone Transdermal Metered Solution should:
 - i. Be a solution for application to the skin; and
 - ii. Contain the active drug ingredient, testosterone, in the same concentration and dosage form as the Reference Listed Drug (RLD); and
 - iii. Contain no differing inactive ingredient or other change in formulation from the RLD that may significantly affect absorption of the active drug ingredient or active moiety.

Because of significant safety concerns pertaining to the transfer of testosterone to others and the current inability of the Office of Generic Drugs (OGD) to adequately determine which new inactive ingredient(s) or change(s) in the formulation may significantly affect the absorption of testosterone, the OGD plans to receive an abbreviated new drug application (ANDA) for a generic version of Testosterone Transdermal Metered Solution only if it has all of the same ingredients as the RLD and the concentration or amount of each inactive ingredient in the test product differs by no more than +/- 5% of the concentration or amount for the same ingredient in the RLD [the generic drug product is qualitatively (Q1) and quantitatively (Q2) the same, i.e., Q1/Q2, to the RLD].

- b. If the generic version of Testosterone Transdermal Metered Solution is not Q1/Q2 to the RLD, the OGD recommends that the applicant contact the Office of New Drugs (OND), Division of Reproduction and Urology Products (DRUP), in order to obtain their recommendations regarding the studies necessary to support the submission of a New Drug Application (NDA) for their drug product.