Contains Nonbinding Recommendations

Draft Guidance on Prasterone

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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: Prasterone

Dosage Form; Route: Insert; vaginal

Strength: 6.5 mg

Recommended Studies: Two studies: in vivo and in vitro

The following studies are recommended to establish bioequivalence of prasterone vaginal insert, provided that the test product is qualitatively (Q1)[1] and quantitatively (Q2)[2] the same as the reference listed drug (RLD):

In Vivo Study:

Study design: Single-dose, two-way crossover in-vivo
Strength: 6.5 mg
Subjects: postmenopausal women
Additional comments: None

Analytes to measure (in appropriate biological fluid): Prasterone in serum

Bioequivalence based on (90% CI): Prasterone

In Vitro Study:

2. Comparative physicochemical characterization on at least three exhibit batches of both the test and reference products. Including the following in vitro comparative physicochemical characterization tests is recommended:
    - melting point
    - viscosity at physiologically relevant temperature
    - hydroxyl value

[1] Q1 (Qualitative sameness) means that the test product uses the same inactive ingredient(s) as the reference product.
[2] Q2 (Quantitative sameness) means that concentrations of the inactive ingredient(s) used in the test product are within ±5% of those used in the reference product.

Additional Information:

Please refer to FDA's guidance entitled, *Comparative Analyses and Related Comparative Use Human Factors Studies*, which provides the Agency's current thinking on the identification and assessment of any differences in the design of the user interface for a proposed generic drug-device combination product when compared to its RLD.

Waiver request of in vivo testing: Not applicable

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).