

Draft Guidance on Minoxidil

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Active ingredient: Minoxidil

Form/Route: Aerosol, Foam/Topical 5%

I. Waiver option:

- a. To qualify for a waiver of the in vivo bioequivalence (BE) study requirements under 21 CFR 320.22(b)(3), a generic minoxidil topical foam aerosol product must have the same active ingredient in the same concentration and dosage form as the reference listed drug product (RLD) and must not have an inactive ingredient or other change in formulation from the RLD that may significantly affect systemic or local availability.
- b. For a topical drug product with inactive ingredients that differ from the RLD or are present in significantly different amounts [as permitted by the chemistry, manufacturing and controls regulations for abbreviated new drug applications, 21 CFR 314.94(a)(9)(v)], the regulation specifies that the applicant must identify and characterize the differences and provide information demonstrating that the differences do not affect the safety or efficacy of the proposed drug product.
- c. To support the waiver request, data from the following comparative in vitro assays is requested:
 - Microscopic Birefringence Analysis on the dispensed foam after complete collapse to determine whether any crystals of undissolved minoxidil form during dispensing.
 - Time to Break Analysis, conducted at 30°C, 33°C, 35°C, and 40°C. Time to break is the time from dispensing to complete foam collapse (break). The testing should be done on at least 3 different lots of the RLD and at least 3 lots of the test product (with each lot manufactured separately).
 - Weight per volume of uncollapsed foam.

II. In Vivo option:

Recommended studies: 1 study

Type of study: Clinical Endpoint Bioequivalence (BE) Study

Design: Randomized, double blind, parallel, placebo-controlled in vivo

Strength: 5%

Subjects: Healthy males with hair loss of the scalp.

Additional comments: FDA recommends submitting a protocol for review and comment prior to conducting the study.

Analytes to measure (in appropriate biological fluid): Not Applicable

Bioequivalence based on (90% CI): Clinical endpoint (in vivo option)

Dissolution test method and sampling times: Not Applicable