

Draft Guidance on Clobetasol Propionate

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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 the 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:	Clobetasol Propionate
Form/Route:	Solution/Topical
Recommended study:	Request for Waiver of In vivo Bioequivalence Study Requirements

Bioequivalence study recommendations:

To qualify for a waiver of the in vivo bioequivalence (BE) study requirements under 21 CFR 320.22(b)(3), a generic clobetasol propionate topical solution 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.

For a topical drug product that differs from the RLD in inactive ingredients [as permitted by the chemistry, manufacturing and controls regulations for abbreviated new drug applications (ANDAs), 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. If the generic clobetasol propionate topical solution product has different inactive ingredients compared to the RLD or differences in the amounts of the same inactive ingredients that are proportionally more than +/- 5% compared to the RLD, then the Office of Generic Drugs (OGD) may request a bioequivalence study with clinical endpoints to determine bioequivalence between the products.

For products applied to the scalp, differences in surfactants or potential penetration enhancers may change the distribution of the product over the scalp or penetration of the drug into the diseased tissues. Therefore, clinical endpoint bioequivalence studies are requested for generic scalp products with differences in these ingredients that are proportionally more than +/- 5% compared to the RLD.