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Draft Guidance on Selenium Sulfide

May 2025

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

Active Ingredient: Selenium sulfide

Dosage Form: Lotion/shampoo

Route: Topical

Strength: 2.5%

Recommended Studies: Characterization tests

Acceptable comparative physicochemical and structural (Q3) characterization of the test product and reference standard should establish that they are the same dosage form, with identical strength. Refer to the most recent version of the FDA guidance for industry on *Physicochemical and Structural (Q3) Characterization of Topical Drug Products Submitted in ANDAs*[a] for additional information regarding appropriate comparative Q3 characterization tests. In addition, adequate information should be provided to ensure that the proposed formulation of the test product will not affect the foamability of the lotion/shampoo and thereby the performance of the drug product.

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[a] For the most recent version of a guidance, check the FDA guidance website at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.