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Draft Guidance on Erythromycin

October 2022

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Active Ingredient: Erythromycin

Dosage Form; Route: Gel; topical

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.

Revision History: Recommended October 2017; Revised October 2022

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