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Alembic Pharma's JV Aleor Dermaceuticals bags US FDA approval for testosterone topical solution

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Alembic Pharmaceuticals announced that its joint venture Aleor Dermaceuticals (Aleor) has received final approval from the US Food & Drug Administration (US FDA) for its Abbreviated
New Drug Application (ANDA) for Testosterone Topical Solution USP, 30 mg per pump actuation. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Axiron Topical Solution, 30 mg per pump actuation, of Eli Lilly and Company (Lilly).

Testosterone Topical Solution USP, 30 mg per pump actuation is indicated for replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone: Primary hypogonadism (congenital or acquired) and Hypogonadotropic hypogonadism (congenital or acquired).

Testosterone Topical Solution USP, 30 mg per pump actuation has an estimated market size of $21 million for twelve months ending March 2021 according to IQVIA. Alembic has a cumulative total of 145 ANDA approvals (127 final approvals and 18 tentative approvals) from US FDA.