

PRESS RELEASE

16th June, 2021, Vadodara, India

Alembic Pharmaceuticals announces its joint venture Aleor Dermaceuticals receives USFDA Final Approval for Testosterone Topical Solution USP, 30 mg per pump actuation.

Alembic Pharmaceuticals Limited (Alembic) today announced that its joint venture Aleor Dermaceuticals Limited (Aleor) has received final approval from the US Food & Drug Administration (USFDA) 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 US\$ 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 USFDA.

About Alembic Pharmaceuticals Limited

Alembic Pharmaceuticals Limited, a vertically integrated research and development pharmaceutical company, has been at the forefront of healthcare since 1907. Headquartered in India, Alembic is a publicly listed company that manufactures and markets generic pharmaceutical products all over the world. Alembic's state of the art research and manufacturing facilities are approved by regulatory authorities of many developed countries including the USFDA. Alembic is one of the leaders in branded generics in India. Alembic's brands, marketed through a marketing team of over 5000 are well recognized by doctors and patients.

Information about the company can be found at <http://www.alembicpharmaceuticals.com/>; (Reuters: ALEM.NS) (Bloomberg: ALPM) (NSE: APLLTD) (BSE: 533573).

About Aleor Dermaceuticals Limited

Aleor is a 60:40 joint venture between Alembic and Orbicular Pharmaceutical Technologies Pvt Ltd (Orbicular) formed in Apr'16 focusing on commercialising dermatology products globally.

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