

PRESS RELEASE

17th November, 2021, Vadodara, India

Alembic Pharmaceuticals announces its joint venture Aleor Dermaceuticals receives USFDA Final Approval for Mupirocin Cream USP, 2%.

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 Mupirocin Cream USP, 2%. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Bactroban Cream, 2%, of SmithKline Beecham(Cork) Ltd, Ireland (SmithKline). Mupirocin Cream USP, 2% is indicated for the treatment of secondarily infected traumatic skin lesions (up to 10 cm in length or 100 cm² in area) due to susceptible strains of *S. aureus* and *S. pyogenes*. Aleor has been granted a Competitive Generic Therapies (CGT) designation for this ANDA and it is eligible for 180 days of CGT exclusivity as it is the first approved applicant.

Mupirocin Cream USP, 2% has an estimated market size of US\$ 28 million for twelve months ending Jun 2021 according to IQVIA.

Alembic has received year to date (YTD) 13 approvals (10 final approvals and 3 tentative approvals) and a cumulative total of 152 ANDA approvals (133 final approvals and 19 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: APL LTD) (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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