

PRESS RELEASE

1st April, 2021, Vadodara, India

Alembic Pharmaceuticals announces its joint venture Aleor Dermaceuticals receives USFDA Final Approval for Nystatin and Triamcinolone Acetonide Cream USP, 100,000 units/gram and 1 mg/gram.

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 Nystatin and Triamcinolone Acetonide Cream USP, 100,000 units/gram and 1 mg/gram. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Nystatin and Triamcinolone Acetonide Cream USP, 100,000 units/gram and 1 mg/gram, of Taro Pharmaceuticals U.S.A. Inc. Nystatin and Triamcinolone Acetonide Cream, USP is indicated for the treatment of cutaneous candidiasis; it has been demonstrated that the nystatin-steroid combination provides greater benefit than the nystatin component alone during the first few days of treatment.

Nystatin and Triamcinolone Acetonide Cream, USP has an estimated market size of US\$ 19 million for twelve months ending December 2020 according to IQVIA.

Alembic has a cumulative total of 139 ANDA approvals (123 final approvals and 16 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: APLTLD) (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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