

PRESS RELEASE

28th June, 2024, Vadodara, India

Alembic Pharmaceuticals announces USFDA Final Approval for Doxycycline Capsules, 40 mg

Alembic Pharmaceuticals Limited (Alembic) today announced that it has received final approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Doxycycline Capsules, 40 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Oracea Capsules, 40 mg, of Galderma Laboratories, L.P. (Galderma). Doxycycline capsules are indicated for the treatment of only inflammatory lesions (papules and pustules) of rosacea in adult patients. Refer label for a detailed indication.

Doxycycline Capsules, 40 mg have an estimated market size of US\$ 123 million for twelve months ending March 2024 according to IQVIA.

Alembic has a cumulative total of 205 ANDA approvals (179 final approvals and 26 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 Alembic can be found at <https://www.alembicpharmaceuticals.com/>;
(Reuters: ALEM.NS) (Bloomberg: ALPM) (NSE: APLLTD) (BSE: 533573)

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