

PRESS RELEASE

21st March, 2022, Vadodara, India

Alembic Pharmaceuticals receives USFDA Final Approval for Lacosamide Tablets USP, 50 mg, 100 mg, 150 mg, and 200 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 Lacosamide Tablets USP, 50 mg, 100 mg, 150 mg, and 200 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) Vimpat Tablets, 50 mg, 100 mg, 150 mg, and 200 mg, of UCB, Inc. Lacosamide Tablets are indicated for the treatment of partial-onset seizures in patients 4 years of age and older. It may not be indicated for certain other uses due to unexpired exclusivities for the RLD for such uses.

Lacosamide Tablets, 50 mg, 100 mg, 150 mg, and 200 mg, have an estimated market size of US\$ 1.67 billion for twelve months ending December 2021 according to IQVIA.

Alembic has received year to date (YTD) 23 approvals (16 final approvals and 7 tentative approvals) and a cumulative total of 161 ANDA approvals (139 final approvals and 22 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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