

PRESS RELEASE

22nd July 2019, Vadodara, India

Alembic Pharmaceuticals receives USFDA Approval for Pregabalin Capsules, 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg, and 300 mg.

Alembic Pharmaceuticals Limited today announced that the Company has received approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Pregabalin Capsules, 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg, and 300 mg. The approved ANDA is therapeutically equivalent to the reference listed drug (RLD), Lyrica Capsules, 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg, and 300 mg, of PF Prism CV. Pregabalin Capsule is indicated for management of neuropathic pain associated with diabetic peripheral neuropathy, management of postherpetic neuralgia, adjunctive therapy for the treatment of partial-onset seizures in patients 17 years of age and older, management of fibromyalgia and management of neuropathic pain associated with spinal cord injury. Alembic had previously received tentative approval for this ANDA.

Pregabalin Capsules have an estimated market size of US\$ 5.47 billion for twelve months ending December 2018 according to IQVIA.

Alembic now has a total of 98 ANDA approvals (88 final approvals and 10 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)

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