

PRESS RELEASE

12th Dec, 2017, Vadodara, India

Alembic Pharmaceuticals receives USFDA Approval for Darifenacin Extended-Release Tablets, 7.5 mg and 15 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) Darifenacin Extended-Release Tablets, 7.5 mg and 15 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) Enablex® Extended-Release Tablets, 7.5 mg and 15 mg, of Allergan Pharmaceuticals. Darifenacin Extended-Release Tablets are indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency and frequency.

Darifenacin Extended-Release Tablets, 7.5 mg and 15 mg, have an estimated market size of US\$ 64 million for twelve months ending December 2016 according to IMS.

Alembic now has a total of 70 ANDA approvals (62 final approvals and 8 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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