

PRESS RELEASE

11th July, 2018, Vadodara, India

Alembic Pharmaceuticals receives USFDA Tentative Approval for Iloperidone Tablets, 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg and 12 mg.

Alembic Pharmaceuticals Limited today announced that the company has received tentative approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Iloperidone tablets, 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg and 12 mg. The tentatively approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Fanapt Tablets, 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg and 12 mg, of Vanda Pharmaceuticals, Inc. Iloperidone tablets are indicated for the treatment of schizophrenia in adults.

Iloperidone Tablets have an estimated market size of US\$ 128 million for twelve months ending December 2017 according to IQVIA.

Alembic now has a total of 74 ANDA approvals (65 final approvals and 9 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)

For more information contact:

Ajay Kumar Desai	Mitanshu Shah
Phone: +91 22 - 306 11681	Phone: +91 265 - 3007630
Email: ajay.desai@alembic.co.in	Email: mitanshu.shah@alembic.co.in



ALEMBIC PHARMACEUTICALS LIMITED

REGD. OFFICE : ALEMBIC ROAD, VADODARA - 390 003. • TEL : (0265) 2280550, 2280880 • FAX : (0265) 2281229
website : www.alembicpharmaceuticals.com • E-mail : alembic@alembic.co.in • CIN : L24230GJ2010PLC061123