

PRESS RELEASE

07th April, 2017, Vadodara, India

Alembic Pharmaceuticals receives USFDA Approval for Fluoxetine Hydrochloride Tablets

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) for Fluoxetine Hydrochloride Tablets, 10 mg and 20mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) Prozac® Tablets, 10 mg and 20mg, of Eli Lilly and Company. Fluoxetine Hydrochloride Tablets are indicated for the treatment of Major Depressive Disorder (MDD) and Obsessive Compulsive Disorder (OCD) in adult and pediatric patients. Fluoxetine Tablets are also indicated for treatment of binge eating and vomiting behaviour in moderate to severe Bulimia Nervosa and acute treatment of Panic Disorder, in adult patients.

Fluoxetine Hydrochloride Tablets have an estimated market size of US\$ 120 million for twelve months ending December 2015 according to IMS.

Alembic now has a total of 53 ANDA approvals (47 final approvals and 6 tentative approvals) from the 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. INDIA • TEL : +91-0265-2280550 • FAX : +91-0265-2282837

Website : www.alembic-india.com • E-mail : alembic@alembic.co.in

CIN: L24230GJ2010PLC061123