

PRESS RELEASE

4th July, 2017, Vadodara, India

Alembic Pharmaceuticals receives USFDA Tentative Approval for Vardenafil Hydrochloride Orally Disintegrating Tablets

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 Vardenafil Hydrochloride Orally Disintegrating Tablets, 10mg. The tentatively approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) STAXYN® Orally Disintegrating Tablets, 10mg, of Bayer Healthcare and is used under license by GlaxoSmithKline. Vardenafil Hydrochloride Orally Disintegrating Tablets, are indicated for the treatment of erectile dysfunction.

Vardenafil Hydrochloride Orally Disintegrating Tablets have an estimated market size of US\$ 9.5 million for twelve months ending December 2016 according to IMS. Alembic is currently in litigation with Bayer in District Court of Delaware and the launch of this product will depend on the outcome of litigation.

Alembic now has a total of 59 ANDA approvals (52 final approvals and 7 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 Phone: +91 22 - 306 11681 Email: ajay.desai@alembic.co.in	Mitanshu Shah Phone: +91 265 - 3007630 Email: mitanshu.shah@alembic.co.in
--	--



ALEMBIC PHARMACEUTICALS LIMITED