Alembic
Touching Lives over 100 years

PRESS RELEASE

11th June, 2018, Vadodara, India

Alembic Pharmaceuticals receives USFDA Approval for Bupropion Hydrochloride Tablets USP, 75 mg and 100 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) Bupropion Hydrochloride Tablets USP, 75 mg and 100 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Wellbutrin® Tablets, 75 mg and 100 mg, of GlaxoSmithKline LLC. Bupropion Hydrochloride Tablets USP, 75 mg and 100 mg is indicated for the treatment of major depressive disorder.

Bupropion Hydrochloride Tablets USP, 75 mg and 100 mg, have an estimated market size of US$ 37 million for twelve months ending December 2017 according to IMS.

Alembic now has a total of 72 ANDA approvals (64 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: APLLTD) (BSE: 533573)

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