

PRESS RELEASE

13th January, 2020, Vadodara, India

Alembic Pharmaceuticals receives USFDA Final Approval for Vilazodone Hydrochloride Tablets, 10 mg, 20 mg, and 40 mg.

Alembic Pharmaceuticals Limited (Alembic) today announced that the Company has received final approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Vilazodone Hydrochloride Tablets, 10 mg, 20 mg, and 40 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Viibryd Tablets, 10 mg, 20 mg, and 40 mg, of Allergan Sales, LLC (Allergan). Vilazodone Hydrochloride Tablets are indicated for the treatment of major depressive disorder.

Vilazodone Hydrochloride Tablets, 10 mg, 20 mg, and 40 mg have an estimated market size of US\$ 469 million for twelve months ending September 2019 according to IQVIA.

Alembic had previously received tentative approval for this ANDA. Alembic was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification and hence is eligible for 180 days of shared exclusivity. The launch of this product will be as per settlement agreement with Allergan.

Alembic has a cumulative total of 110 ANDA approvals (98 final approvals and 12 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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