

PRESS RELEASE

20th April, 2022, Vadodara, India

Alembic Pharmaceuticals receives USFDA Tentative Approval for Ivabradine Tablets, 5 mg and 7.5 mg.

Alembic Pharmaceuticals Limited (Alembic) today announced that it has received tentative approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Ivabradine Tablets, 5 mg and 7.5 mg. The tentatively approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) Corlanor Tablets, 5 mg and 7.5 mg, of Amgen Inc. (Amgen). Ivabradine Tablets are indicated to reduce the risk of hospitalization for worsening heart failure in adult patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction $\leq 35\%$, who are in sinus rhythm with resting heart rate ≥ 70 beats per minute and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use. Ivabradine Tablets are indicated for the treatment of stable symptomatic heart failure due to dilated cardiomyopathy (DCM) in pediatric patients aged 6 months and older, who are in sinus rhythm with an elevated heart rate. It may not be indicated for certain other uses due to unexpired exclusivities for the RLD for such uses.

Ivabradine Tablets, 5 mg and 7.5 mg have an estimated market size of US\$ 102 million for twelve months ending December 2021 according to IQVIA.

Alembic has received a cumulative total of 164 ANDA approvals (140 final approvals and 24 tentative approvals) from USFDA.

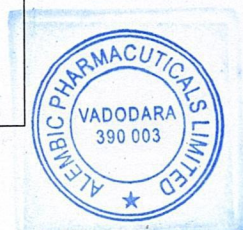
About Alembic Pharmaceuticals Limited

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 Alembic can be found at <https://www.alembicpharmaceuticals.com/>; (Reuters: ALEM.NS) (Bloomberg: ALPM) (NSE: APL LTD) (BSE: 533573)

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