

PRESS RELEASE

20th October, 2024, Vadodara, India

Alembic Pharmaceuticals announces USFDA Final Approval for Diltiazem Hydrochloride Extended-Release Capsules USP, 120 mg, 180 mg, and 240 mg.

Alembic Pharmaceuticals Limited (Alembic) today announced that it has received final approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Diltiazem Hydrochloride Extended-Release Capsules USP, 120 mg, 180 mg, and 240 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Dilacor XR Extended-Release Capsules, 120 mg, 180 mg, and 240 mg, of Allergan Sales LLC (Allergan). Diltiazem Hydrochloride Extended-Release Capsules USP are indicated for the treatment of hypertension. Diltiazem hydrochloride may be used alone or in combination with other antihypertensive medications, such as diuretics. It is also indicated for the management of chronic stable angina. Refer label for a detailed indication.

Diltiazem Hydrochloride Extended-Release Capsules USP, 120 mg, 180 mg, and 240 mg have an estimated market size of US\$ 28.2 million for twelve months ending June 2024 according to IQVIA.

Alembic has a cumulative total of 217 ANDA approvals (190 final approvals and 27 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).

For more information contact:

Ajay Kumar Desai

Phone: +91 22-66953681 | 7045504460

Email: ajay.desai@alembic.co.in



ALEMBIC PHARMACEUTICALS LIMITED

REGD.OFFICE: ALEMBIC ROAD, VADODARA - 390 003. •TEL: (0265) 2280550, 2280880•FAX: (0265) 2281229
Website : www.alembicpharmaceuticals.com• E-mail : alembic@alembic.co.in• CIN : L24230GJ2010PLC061123