

15th November, 2025 Vadodara, India

Alembic Pharmaceuticals Limited announces USFDA Final Approval for Diltiazem Hydrochloride Tablets USP, 30 mg, 60 mg, 90 mg, and 120 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 Tablets USP, 30 mg, 60 mg, 90 mg, and 120 mg. The approved ANDA is therapeutically equivalent to the reference listed drug (RLD), Cardizem Tablets, 30 mg, 60 mg, 90 mg, and 120 mg, of Bausch Health US, LLC. Diltiazem hydrochloride tablets are indicated for the management of chronic stable angina and angina due to coronary artery spasm. Refer label for a detailed indication.

Alembic has a cumulative total of 230 ANDA approvals (210 final approvals and 20 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 field force of over 5500 are well recognized by doctors and patients.

Information about the Company can be found at www.alembicpharmaceuticals.com; (Reuters:ALEM.NS) (Bloomberg:ALPM) (NSE:APLLTD) (BSE:533573)

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