



Date: 11th November, 2024

To,
The Manager,
Department of Corporate Services,
BSE Limited
P. J. Towers, Dalal Street,
Fort, Mumbai – 400 001
BSE Scrip Code: 533573

To,
The Manager,
Listing Department,
National Stock Exchange of India Ltd.
'Exchange Plaza', Bandra Kurla Complex,
Bandra (E), Mumbai – 400 051
NSE Symbol: APLLTD

Dear Sir/Madam,

Sub: Alembic Pharmaceuticals receives USFDA Final Approval for Diltiazem Hydrochloride Extended-Release Capsules USP, 120 mg, 180 mg, 240 mg, 300 mg, and 360 mg.

With reference to the captioned subject, this is to inform the exchange that the Company has received US Food & Drug Administration (USFDA) Final Approval for Diltiazem Hydrochloride Extended-Release Capsules USP, 120 mg, 180 mg, 240 mg, 300 mg, and 360 mg.

Please find enclosed herewith our press release.

We request you to kindly take the same on record.

Thanking you,

Yours faithfully,

For Alembic Pharmaceuticals Limited

Manisha Saraf
Company Secretary
Encl.: A/a.

ALEMBIC PHARMACEUTICALS LIMITED

REGD. OFFICE: ALEMBIC ROAD, VADODARA - 390 003. • TEL: (0265) 2280550, 2280880 • FAX: (0265) 2281229
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PRESS RELEASE

11th November, 2024, Vadodara, India

Alembic Pharmaceuticals announces USFDA Final Approval for Diltiazem Hydrochloride Extended-Release Capsules USP, 120 mg, 180 mg, 240 mg, 300 mg, and 360 mg.

Alembic Pharmaceuticals Limited (Alembic) announced that it has received Final Approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Diltiazem Hydrochloride Extended-Release Capsules USP, 120 mg, 180 mg, 240 mg, 300 mg, and 360 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Cardizem CD Extended-Release Capsules, 120 mg, 180 mg, 240 mg, 300 mg, and 360 mg, of Bausch Health US, LLC. 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. It is also indicated for the management of chronic stable angina and angina due to coronary artery spasm. Refer label for a detailed indication.

Diltiazem Hydrochloride Extended-Release Capsules USP, 120 mg, 180 mg, 240 mg, 300 mg, and 360 mg have an estimated market size of US\$105.3 million for twelve months ending June 2024 according to IQVIA.

Alembic has a cumulative total of 218 ANDA approvals (191 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 field force of over 5200 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)

For more information, contact:

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