

Date: 15<sup>th</sup> November, 2025

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 Limited receives USFDA Final Approval for Diltiazem Hydrochloride Tablets USP, 30 mg, 60 mg, 90 mg, and 120 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 Tablets USP, 30 mg, 60 mg, 90 mg, and 120 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**

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Website : [www.alembicpharmaceuticals.com](http://www.alembicpharmaceuticals.com) • E-mail : [alembic@alembic.co.in](mailto:alembic@alembic.co.in) • CIN : L24230GJ2010PLC061123

## PRESS RELEASE

15<sup>th</sup> 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](http://www.alembicpharmaceuticals.com); (Reuters:ALEM.NS) (Bloomberg:ALPM) (NSE:APLLTD) (BSE:533573)

For more information, contact:

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