

Date: 13<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 Dexlansoprazole Delayed-Release Capsules, 30 mg and 60 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 Dexlansoprazole Delayed-Release Capsules, 30 mg and 60 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  
Website : [www.alembicpharmaceuticals.com](http://www.alembicpharmaceuticals.com) • E-mail : [alembic@alembic.co.in](mailto:alembic@alembic.co.in) • CIN : L24230GJ2010PLC061123

## PRESS RELEASE

13<sup>th</sup> November, 2025 Vadodara, India

### **Alembic Pharmaceuticals Limited announces USFDA Final Approval Dexlansoprazole Delayed-Release Capsules, 30 mg and 60 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) Dexlansoprazole Delayed-Release Capsules, 30 mg and 60 mg. The approved ANDA is therapeutically equivalent to the reference listed drug (RLD), Dexilant Delayed-Release Capsules, 30 mg and 60 mg, of Takeda Pharmaceuticals USA, Inc. (Takeda). Dexlansoprazole delayed-release capsules are a proton pump inhibitor (PPI) indicated in patients 12 years of age and older for: (i) Healing of all grades of erosive esophagitis (EE), (ii) Maintenance of healed EE and relief of heartburn, and (iii) Treatment of symptomatic non-erosive gastroesophageal reflux disease (GERD). Refer label for a detailed indication.

Dexlansoprazole Delayed-Release Capsules, 30 mg and 60 mg, have an estimated market size of US\$ 285 million for twelve months ending September 2025 according to IQVIA.

Alembic has a cumulative total of 229 ANDA approvals (209 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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