Date: 7th April, 2026

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 Dapagliflozin Tablets, 5 mg and 10 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 Dapagliflozin Tablets, 5 mg and 10 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
Digitally signed by MANISHA SARAF
Date: 2026.04.07 12:07:17 +05'30'
Manisha Saraf
Company Secretary
Encl.: A/a.

PRESS RELEASE

7th April, 2026 Vadodara, India

Alembic Pharmaceuticals Limited announces USFDA Final Approval for Dapagliflozin Tablets, 5 mg and 10 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) Dapagliflozin Tablets, 5 mg and 10 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Farxiga Tablets, 5 mg and 10 mg, of AstraZeneca AB (AstraZeneca). Dapagliflozin tablet is a sodium-glucose cotransporter 2 (SGLT2) inhibitor indicated: i) to reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and either established cardiovascular disease or multiple cardiovascular risk factors, and ii) as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Refer label for a detailed indication.

Alembic was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification for Dapagliflozin Tablets, 5 mg and 10 mg. Therefore, with this approval, Alembic is eligible for 180 days of shared generic drug exclusivity.

Dapagliflozin tablets, 5 mg and 10 mg, have an estimated market size of US$ 10,487 million for twelve months ending December 2025 according to IQVIA.

Alembic has a cumulative total of 235 ANDA approvals (217 final approvals and 18 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)

For more information, contact:
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