

PRESS RELEASE

13th November, 2025 Vadodara, India

Alembic Pharmaceuticals Limited announces USFDA Final Approval Dexamisoprazole 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) Dexamisoprazole 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). Dexamisoprazole 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.

Dexamisoprazole 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; (Reuters:ALEM.NS) (Bloomberg:ALPM) (NSE:APLLTD) (BSE:533573)

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