

PRESS RELEASE

28th July, 2026 Vadodara, India

Alembic Pharmaceuticals Limited receives USFDA Final Approval for Prucalopride Tablets, 1 mg and 2 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) Prucalopride Tablets, 1 mg and 2 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Motegrity Tablets, 1 mg and 2 mg, of Takeda Pharmaceuticals USA Inc. Prucalopride tablets are serotonin-4 receptor agonist indicated for the treatment of chronic idiopathic constipation (CIC) in adults. Refer label for a detailed indication.

Prucalopride Tablets, 1 mg and 2 mg, have an estimated market size of US\$ 100 million for twelve months ending March 2026 according to IQVIA.

Alembic has a cumulative total of 245 ANDA approvals (225 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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