

PRESS RELEASE

27th March, 2026 Vadodara, India

Alembic Pharmaceuticals Limited announces USFDA Final Approval for Paroxetine Extended-Release Tablets USP, 12.5 mg.

Alembic Pharmaceuticals Limited (Alembic) today announced that it has received final approval from the US Food & Drug Administration (USFDA) for its supplemental Abbreviated New Drug Application (sANDA) Paroxetine Extended-Release Tablets USP, 12.5 mg. The approved sANDA is therapeutically equivalent to the reference listed drug product (RLD), Paxil CR Tablets, 12.5 mg, of Apotex Inc. Paroxetine extended-release tablets are indicated for the treatment of Major depressive disorder (MDD), Panic disorder (PD), Social anxiety disorder (SAD), and Premenstrual dysphoric disorder (PMDD). Refer label for a detailed indication.

Alembic has a cumulative total of 235 ANDA approvals (216 final approvals and 19 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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