PRESS RELEASE

25th September, 2025 Vadodara, India

Alembic Pharmaceuticals Limited announces USFDA Final Approval for Paroxetine Extended-Release Tablets USP, 25 mg and 37.5 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) Paroxetine Extended-Release Tablets USP, 25 mg and 37.5 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Paxil CR Extended-Release Tablets, 25 mg and 37.5 mg, of Apotex Inc. Paroxetine Extended-Release Tablets USP, 25 mg and 37.5 mg, 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 226 ANDA approvals (205 final approvals and 21 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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