PRESS RELEASE

5th June, 2026 Vadodara, India

Alembic Pharmaceuticals Limited announces USFDA Final Approval for Haloperidol Tablets, USP, 1 mg, 2 mg, 5 mg, 10 mg, and 20 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) Haloperidol Tablets, USP, 1 mg, 2 mg, 5 mg, 10 mg, and 20 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Haldol Tablets, 1 mg, 2 mg, 5 mg, 10 mg, and 20 mg, of Ortho McNeil Pharmaceutical (Ortho McNeil). Haloperidol Tablets are indicated for: i) use in the management of manifestations of psychotic disorders and ii) the control of tics and vocal utterances of Tourette's Disorder in children and adults. Refer label for a detailed indication.

Haloperidol Tablets, USP, 1 mg, 2 mg, 5 mg, 10 mg, and 20 mg, have an estimated market size of US$ 27 million for twelve months ending March 2026 according to IQVIA.

Alembic has a cumulative total of 240 ANDA approvals (221 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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