

PRESS RELEASE

29th June, 2025 Vadodara, India

Alembic Pharmaceuticals Limited announces USFDA Final Approval for Doxorubicin Hydrochloride Liposome Injection 20 mg/10 mL (2 mg/mL) and 50 mg/25 mL (2 mg/mL) Single-Dose Vials.

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) for Doxorubicin Hydrochloride Liposome Injection, 20 mg/10 mL (2 mg/mL) and 50 mg/25 mL (2 mg/mL) Single-Dose Vials. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Doxil Liposome Injection, 20 mg/10 mL (2 mg/mL) and 50 mg/25 mL (2 mg/mL), of Baxter Healthcare Corporation.

Doxorubicin Hydrochloride Liposome Injection is indicated for the treatment of Ovarian Cancer, AIDS-Related Kaposi's Sarcoma, and Multiple Myeloma. Refer label for a detailed indication.

Doxorubicin Hydrochloride Liposome Injection, 20 mg/10 mL (2 mg/mL) and 50 mg/25 mL (2mg/mL) Single-Dose Vials have an estimated market size of US\$ 29 million for twelve months ending March 2025 according to IQVIA.

Alembic has a cumulative total of 224 ANDA approvals (201 final approvals and 23 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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