



PRESS RELEASE

3rd November, 2022, Vadodara, India

Alembic Pharmaceuticals announces its second injectable product approval from its General Sterile Facility - Final Approval for Ketorolac Tromethamine Injection USP.

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 Ketorolac Tromethamine Injection USP, 15 mg/mL, 30 mg/mL, and 60 mg/2 mL (30 mg/mL) Single Dose Vials.

This is the second injectable product approval from our General Sterile Facility (F-3) which was inspected in August, 2022.

The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Toradol Injection, 15 mg/mL, 30 mg/mL, and 60 mg/2 mL, of Roche Palo Alto, LLC (Roche). Ketorolac Tromethamine is indicated for the short-term (≤ 5 days) management of moderately severe acute pain in adult patients. Refer to our label for full indication.

Ketorolac Tromethamine Injection USP has an estimated market size of US\$ 59 million for twelve months ending June 2022 according to IQVIA.

Alembic has a cumulative total of 175 ANDA approvals (151 final approvals and 24 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 marketing team of over 5000 are well recognized by doctors and patients.

Information about Alembic can be found at <https://www.alembicpharmaceuticals.com/>; (Reuters: ALEM.NS) (Bloomberg: ALPM) (NSE: APLLTD) (BSE: 533573).

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