

PRESS RELEASE

12th April, 2022, Vadodara, India

Alembic Pharmaceuticals announces its wholly owned subsidiary, Aleor Dermaceuticals Limited receives USFDA Final Approval for Lidocaine and Prilocaine Cream USP, 2.5%/2.5%.

Alembic Pharmaceuticals Limited (Alembic) today announced that its wholly owned subsidiary, Aleor Dermaceuticals Limited (Aleor) has received final approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Lidocaine and Prilocaine Cream USP, 2.5%/2.5%. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) EMLA Cream, 2.5%/2.5%, of Teva Branded Pharmaceutical Products R&D, Inc. Lidocaine 2.5% and Prilocaine 2.5% cream (a eutectic mixture of lidocaine 2.5% and prilocaine 2.5%) is indicated as a topical anesthetic for use on normal intact skin for local analgesia and genital mucous membranes for superficial minor surgery and as pretreatment for infiltration anesthesia. Lidocaine 2.5% and Prilocaine 2.5% cream is not recommended in any clinical situation when penetration or migration beyond the tympanic membrane into the middle ear is possible because of the ototoxic effects observed in animal studies

Lidocaine and Prilocaine Cream USP, 2.5%/2.5% has an estimated market size of US\$29 million for twelve months ending Dec. 2021 according to IQVIA.

Alembic has received a cumulative total of 163 ANDA approvals (140 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 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).

For more information contact:

Ajay Kumar Desai	Mitanshu Shah
Phone: +91 22 - 306 11681	Phone: +91 265 - 6637630
Email: ajay.desai@alembic.co.in	Email: mitanshu.shah@alembic.co.in



ALEMBIC PHARMACEUTICALS LIMITED

REGD. OFFICE : ALEMBIC ROAD, VADODARA - 390 003, INDIA • TEL : +91-265-2280550 • FAX : +91-265-2282837
Website : www.alembicpharmaceuticals.com • E-mail : alembic@alembic.co.in
CIN : L24230GJ2010PLC061123