



PRESS RELEASE

22nd December, 2022, Vadodara, India

Alembic Pharmaceuticals announces its first product approval from its Formulation Division IV, Jarod Facility.

Alembic Pharmaceuticals Limited (Alembic) today announced that it has received PAS (Prior Approval Supplement) approval from the US Food & Drug Administration (USFDA) for its Supplemental Abbreviated New Drug Application (sANDA) Pregabalin Capsules, 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg and 300 mg.

The sANDA, submitted as "Prior Approval Supplement," provides for an alternate drug product manufacturing site - Alembic Pharmaceuticals Limited, Formulation Division IV, Jarod, Gujarat, India for previously approved ANDA from Panelav Facility (F-I). This is the first product approval from Jarod Facility which was inspected in Dec 2022.

The approved sANDA is therapeutically equivalent to the reference listed drug product (RLD), Lyrica Capsules, of Upjohn. Pregabalin Capsules are indicated for neuropathic pain, postherpetic neuralgia, and other indications. Refer to our label for full indication.

Pregabalin Capsules have an estimated market size of US\$ 244 million for twelve months ending Sep 2022 according to IQVIA.

Alembic has a cumulative total of 178 ANDA approvals (155 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.

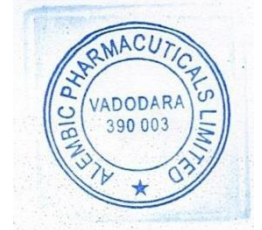
Information about Alembic can be found at <https://www.alembicpharmaceuticals.com/>;
(Reuters: ALEM.NS) (Bloomberg: ALPM) (NSE: APLLTD) (BSE: 533573)

ALEMBIC PHARMACEUTICALS LIMITED

REGD. OFFICE : ALEMBIC ROAD, VADODARA - 390 003. • TEL : (0265) 2280550, 2280880 • FAX : (0265) 2281229
Website : www.alembicpharmaceuticals.com • E-mail : alembic@alembic.co.in • CIN : L24230GJ2010PLC061123

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