

PRESS RELEASE

14th May, 2021, Vadodara, India

Alembic Pharmaceuticals announces USFDA Final Approval for Lurasidone Hydrochloride Tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 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) for Lurasidone Hydrochloride Tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Latuda Tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg, of Sunovion Pharmaceuticals Inc. (Sunovion). Lurasidone Hydrochloride Tablets are indicated for monotherapy treatment of adult and pediatric patients (10 to 17 years) with major depressive episode associated with bipolar I disorder (bipolar depression). Lurasidone Hydrochloride Tablets are also indicated for adjunctive treatment with lithium or valproate in adult patients with major depressive episode associated with bipolar I disorder.

Lurasidone Hydrochloride Tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg have an estimated market size of US\$ 3.7 billion for twelve months ending December 2020 according to IQVIA. Alembic has settled the case with Sunovion and will launch its generic as per the terms of settlement.

Alembic has a cumulative total of 144 ANDA approvals (126 final approvals and 18 tentative approvals) from USFDA.

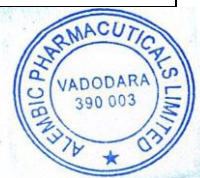
About Alembic Pharmaceuticals Limited

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 <http://www.alembicpharmaceuticals.com/>;
(Reuters: ALEM.NS) (Bloomberg: ALPM) (NSE: APLLTD) (BSE: 533573)

For more information contact:

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