

PRESS RELEASE

07th November, 2025 Vadodara, India

Alembic Pharmaceuticals Limited announces USFDA Final Approval for Dasatinib Tablets, 20 mg, 50 mg, 70 mg, 80 mg, 100 mg, and 140 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) Dasatinib Tablets, 20 mg, 50 mg, 70 mg, 80 mg, 100 mg, and 140 mg. The approved ANDA is therapeutically equivalent to the reference listed drug (RLD), Sprycel Tablets, 20 mg, 50 mg, 70 mg, 80 mg, 100 mg, and 140 mg, of Bristol-Myers Squibb Company (BMS). Dasatinib tablets are indicated for the treatment of adult patients with: (i) newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase, (ii) chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib, (iii) Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) with resistance or intolerance to prior therapy. Dasatinib tablets are also indicated for the treatment of pediatric patients 1 year of age and older with Ph+ CML in chronic phase. Refer label for a detailed indication.

Dasatinib Tablets, 20 mg, 50 mg, 70 mg, 80 mg, 100 mg, and 140 mg, have an estimated market size of US\$ 1,017 million for twelve months ending September 2025 according to IQVIA.

Alembic has a cumulative total of 227 ANDA approvals (207 final approvals and 20 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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