

PRESS RELEASE

23rd November, 2021, Vadodara, India

Alembic Pharmaceuticals announces USFDA Final Approval for Formoterol Fumarate Inhalation Solution, 20 mcg/2 mL per Unit-Dose Vial.

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 Formoterol Fumarate Inhalation Solution, 20 mcg/2 mL per Unit-Dose Vial. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Perforomist Inhalation Solution, 20 mcg/2 mL per Unit-Dose Vial, of Mylan Specialty, L.P. Formoterol Fumarate Inhalation Solution is a long-acting beta2-adrenergic agonist (beta2-agonist) indicated for long-term, twice daily (morning and evening) administration in the maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

This ANDA has been co-developed in partnership with Orbicular Pharmaceutical Technologies Private Limited.

Formoterol Fumarate Inhalation Solution, 20 mcg/2 mL per Unit-Dose Vial, has an estimated market size of US\$ 310 million for twelve months ending Sep. 2021 according to IQVIA.

Alembic has received year to date (YTD) 14 approvals (11 final approvals and 3 tentative approvals) and a cumulative total of 153 ANDA approvals (134 final approvals and 19 tentative approvals) from USFDA, including this first inhalational ANDA approval.

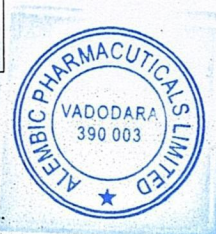
About Alembic Pharmaceuticals Limited

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)

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