

PRESS RELEASE

6th January, 2023, Vadodara, India

Alembic Pharmaceuticals receives USFDA Final Approval for Fesoterodine Fumarate Extended-Release Tablets, 4 mg and 8 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), Fesoterodine Fumarate Extended-Release Tablets, 4 mg and 8 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Toviaz Extended-Release Tablets, 4 mg and 8 mg, of Pfizer Inc. (Pfizer). Fesoterodine Fumarate Extended-Release Tablets are indicated for the treatment of overactive bladder (OAB) in adults with symptoms of urge urinary incontinence, urgency, and frequency. Refer to our label for full indication.

Fesoterodine Fumarate Extended-Release Tablets, 4 mg and 8 mg, have an estimated market size of US\$ 177 million for twelve months ending Sep 2022 according to IQVIA. Alembic had previously received tentative approval for this ANDA.

Alembic has a cumulative total of 179 ANDA approvals (157 final approvals and 22 tentative approvals) from USFDA.

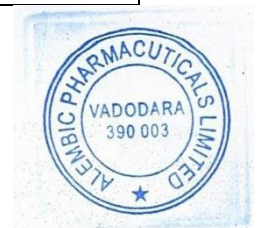
About Alembic Pharmaceuticals Limited

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)

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