

PRESS RELEASE

20th Feb., 2019, Vadodara, India

Alembic Pharmaceuticals announces USFDA Approval for Acetazolamide Extended-Release Capsules, 500 mg.

Alembic Pharmaceuticals Limited (Alembic) today announced that it has received approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Acetazolamide Extended-Release Capsules, 500 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) Diamox Sequels, 500 mg, of Teva Branded Pharmaceutical Products R&D Inc. Acetazolamide Extended-Release Capsules, 500 mg is indicated for adjunctive treatment of: chronic simple (open-angle) glaucoma, secondary glaucoma, and preoperatively in acute angle-closure glaucoma where delay of surgery is desired in order to lower intraocular pressure. Acetazolamide extended-release capsules are also indicated for the prevention or amelioration of symptoms associated with acute mountain sickness despite gradual ascent.

Acetazolamide Extended-Release Capsules, 500 mg has an estimated market size of US\$ 13.1 million for twelve months ending December 2018 according to IQVIA.

Alembic has a cumulative total of 87 ANDA approvals (74 final approvals and 13 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 the company can be found at <http://www.alembicpharmaceuticals.com/>; (Reuters: ALEM.NS) (Bloomberg: ALPM) (NSE: APL LTD) (BSE: 533573)

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