

PRESS RELEASE

15th Feb., 2019, Vadodara, India

Alembic Pharmaceuticals announces USFDA Approval for Moxifloxacin Ophthalmic Solution USP, 0.5%.

Alembic Pharmaceuticals Limited (Alembic) today announced it has received approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Moxifloxacin Ophthalmic Solution USP, 0.5%. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) Vigamox Ophthalmic Solution USP, 0.5%, of Novartis Pharmaceuticals Corporation. Moxifloxacin Ophthalmic Solution USP, 0.5% is indicated for the treatment of bacterial conjunctivitis caused by susceptible strains of certain organisms.

Moxifloxacin Ophthalmic Solution USP, 0.5% has an estimated market size of US\$ 68 million for twelve months ending December 2018 according to IQVIA.

Alembic has a cumulative total of 86 ANDA approvals (73 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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