Alembic
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PRESS RELEASE

10th December, 2018, Vadodara, India

Alembic Pharmaceuticals receives USFDA Approval for Olopatadine Hydrochloride Ophthalmic Solution USP, 0.1%.

Alembic Pharmaceuticals Limited today announced that the company has received approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Olopatadine Hydrochloride Ophthalmic Solution USP, 0.1%. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD Patanol Ophthalmic Solution, 0.1%, of Novartis Pharmaceuticals Corporation. Olopatadine hydrochloride ophthalmic solution USP, 0.1% is indicated for the treatment of the signs and symptoms of allergic conjunctivitis.

Olopatadine hydrochloride ophthalmic solution USP, 0.1%, have an estimated market size of US$ 61 million for twelve months ending December 2017 according to IQVIA.

Alembic has a cumulative total of 83 ANDA approvals (70 final approvals and 13 tentative approvals) from USFDA. This is first ophthalmic dosage form approval for Alembic pharmaceuticals Limited.

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: APLLTD) (BSE: 533573)

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