Alembic
Touching Lives over 100 years

Date: 22nd March, 2019

To,
The Manager,
Listing Department
National Stock Exchange of India Ltd
'Exchange Plaza'
Bandra Kurla Complex, Bandra (E),
Mumbai – 400 051

Dear Sir/Madam,

Sub: Alembic Pharmaceuticals receives USFDA Approval for Azelastine Hydrochloride Ophthalmic Solution, 0.05%.

With reference to the captioned subject, this is to inform the exchange that the Company has received US Food & Drug Administration (USFDA) Approval for Azelastine Hydrochloride Ophthalmic Solution, 0.05%.

Please find enclosed herewith our press release.

We request you to kindly take the same on record.

Thanking you,

Yours faithfully,
For Alembic Pharmaceuticals Limited

Charandeep Singh Saluja
Company Secretary

Encl.: A/a.

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PRESS RELEASE

22nd March 2019, Vadodara, India

Alembic Pharmaceuticals receives USFDA Approval for Azelastine Hydrochloride Ophthalmic Solution, 0.05%.

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) Azelastine Hydrochloride Ophthalmic Solution, 0.05%. The approved ANDA is therapeutically equivalent to the reference listed drug (RLD), Optivar Ophthalmic Solution, 0.05%, of Mylan Specialty L.P. (Mylan). Azelastine Hydrochloride Ophthalmic Solution 0.05% is indicated for the treatment of itching of the eye associated with allergic conjunctivitis.

Azelastine Hydrochloride Ophthalmic Solution, 0.05%, has an estimated market size of US$ 8.5 million for twelve months ending December 2018 according to IQVIA.

Alembic now has a total of 89 ANDA approvals (76 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: APLLTD) (BSE: 533573)

For more information contact:

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