

Date: 26th October, 2020

To,
The Manager,
Department of Corporate Services,
BSE Limited
P. J. Towers, Dalal Street,
Fort, Mumbai – 400 001

Dear Sir/Madam,

Sub: Alembic Pharmaceuticals receives USFDA Final Approval for Timolol Maleate Ophthalmic Gel Forming Solution, 0.25% and 0.5%.

With reference to the captioned subject, this is to inform the exchange that the Company has received US Food & Drug Administration (USFDA) Final Approval for Timolol Maleate Ophthalmic Gel Forming Solution, 0.25% and 0.5%.

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.

PRESS RELEASE

26th October, 2020, Vadodara, India

Alembic Pharmaceuticals announces USFDA Final Approval for Timolol Maleate Ophthalmic Gel Forming Solution, 0.25% and 0.5%.

Alembic Pharmaceuticals Limited (Alembic) today announced it has received final approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Timolol Maleate Ophthalmic Gel Forming Solution, 0.25% and 0.5%. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Timoptic-XE Ophthalmic Gel Forming Solution, 0.25% and 0.5%, of Bausch Health US, LLC. Timolol Maleate Ophthalmic Gel Forming Solution is indicated in the treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma. Alembic has been granted a Competitive Generic Therapies (CGT) designation for this ANDA and it is eligible for 180 days of CGT exclusivity as it is the first approved ANDA.

Timolol Maleate Ophthalmic Gel Forming Solution, 0.25% and 0.5% has an estimated market size of US\$ 71 million for twelve months ending June 2020 according to IQVIA.

This ANDA has been co-developed in partnership with Orbicular Pharmaceutical Technologies Pvt Ltd.

Alembic has a cumulative total of 134 ANDA approvals (117 final approvals and 17 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 <http://www.alembicpharmaceuticals.com/>; (Reuters: ALEM.NS) (Bloomberg: ALPM) (NSE: APLLTD) (BSE: 533573)

For more information contact:

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