

Date: 5th May, 2021

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 Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution USP, 2% 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 Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution USP, 2% 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

5th May, 2021, Vadodara, India

Alembic Pharmaceuticals announces USFDA Final Approval for Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution USP, 2% and 0.5%.

Alembic Pharmaceuticals Limited (Alembic) today announced that it has received final approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution USP, 2% and 0.5%. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Cosopt Ophthalmic Solution, 2% and 0.5%, of Akorn Operating Company LLC. Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution is a combination of dorzolamide hydrochloride carbonic anhydrase inhibitor, and timolol maleate, a beta-adrenergic receptor blocking agent, indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to beta-blockers.

Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution USP, 2% and 0.5% has an estimated market size of US\$ 80 million for twelve months ending December 2020 according to IQVIA.

Alembic has a cumulative total of 143 ANDA approvals (125 final approvals and 18 tentative approvals) from USFDA.

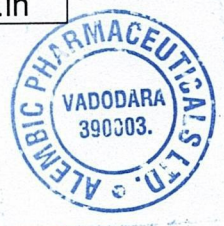
About Alembic Pharmaceuticals Limited

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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ALEMBIC PHARMACEUTICALS LIMITED