

Date: 13<sup>th</sup> August, 2019

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 Approval for Dorzolamide Hydrochloride Ophthalmic Solution USP, 2%.**

With reference to the captioned subject, this is to inform the exchange that the Company has received US Food & Drug Administration (USFDA) Approval for Dorzolamide Hydrochloride Ophthalmic Solution USP, 2%.

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.

**ALEMBIC PHARMACEUTICALS LIMITED**

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website : www.alembicpharmaceuticals.com • E-mail : alembic@alembic.co.in • CIN : L24230GJ2010PLC061123

**PRESS RELEASE**

13<sup>th</sup> August, 2019, Vadodara, India

**Alembic Pharmaceuticals receives USFDA Approval for Dorzolamide Hydrochloride Ophthalmic Solution USP, 2%.**

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) for Dorzolamide Hydrochloride Ophthalmic Solution USP, 2%. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) Trusopt Ophthalmic Solution, 2%, of Merck Sharp & Dohme Corp. Dorzolamide Hydrochloride Ophthalmic Solution is a carbonic anhydrase inhibitor indicated in the treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma.

Dorzolamide Hydrochloride Ophthalmic Solution USP, 2% has an estimated market size of US\$ 35 million for twelve months ending December 2018 according to IQVIA.

Alembic now has a total of 101 ANDA approvals (89 final approvals and 12 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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**ALEMBIC PHARMACEUTICALS LIMITED**