



Date: 20<sup>th</sup> April, 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 Tentative Approval for Alcaftadine Ophthalmic Solution, 0.25%.**

With reference to the captioned subject, this is to inform the exchange that the Company has received US Food & Drug Administration (USFDA) Tentative Approval for Alcaftadine Ophthalmic Solution, 0.25%.

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**

REGD. OFFICE : ALEMBIC ROAD, VADODARA - 390 003. • TEL : (0265) 2280550, 2280880 • FAX : (0265) 2281229  
website : [www.alembicpharmaceuticals.com](http://www.alembicpharmaceuticals.com) • E-mail : [alembic@alembic.co.in](mailto:alembic@alembic.co.in) • CIN : L24230GJ2010PLC061123

**PRESS RELEASE**

20<sup>th</sup> April, 2020, Vadodara, India

**Alembic Pharmaceuticals announces USFDA Tentative Approval for Alcaftadine Ophthalmic Solution, 0.25%.**

Alembic Pharmaceuticals Limited (Alembic) today announced it has received tentative approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Alcaftadine Ophthalmic Solution, 0.25%. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) Lastacft Ophthalmic Solution, 0.25%, of Allergan, Inc. (Allergan). Alcaftadine Ophthalmic Solution is an H1 histamine receptor antagonist indicated for the prevention of itching associated with allergic conjunctivitis.

Alcaftadine Ophthalmic Solution, 0.25% has an estimated market size of US\$ 7 million for twelve months ending December 2019 according to IQVIA.

Alembic has a cumulative total of 120 ANDA approvals (107 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 Alembic can be found at <http://www.alembicpharmaceuticals.com/>; (Reuters: ALEM.NS) (Bloomberg: ALPM) (NSE: APL LTD) (BSE: 533573)

For more information contact:

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