

Date: 15<sup>th</sup> February, 2019

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

Dear Sir/Madam,

# Sub: Alembic Pharmaceuticals receives USFDA Approval for Moxifloxacin Ophthalmic Solution USP, 0.5%.

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

Authorised Signatory Secretarial Department

Encl.: A/a.



### PRESS RELEASE

## 15<sup>th</sup> Feb., 2019, Vadodara, India

## <u>Alembic Pharmaceuticals announces USFDA Approval for Moxifloxacin Ophthalmic</u> <u>Solution USP, 0.5%.</u>

Alembic Pharmaceuticals Limited (Alembic) today announced it has received approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Moxifloxacin Ophthalmic Solution USP, 0.5%. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) Vigamox Ophthalmic Solution USP, 0.5%, of Novartis Pharmaceuticals Corporation. Moxifloxacin Ophthalmic Solution USP, 0.5% is indicated for the treatment of bacterial conjunctivitis caused by susceptible strains of certain organisms.

Moxifloxacin Ophthalmic Solution USP, 0.5% has an estimated market size of US\$ 68 million for twelve months ending December 2018 according to IQVIA.

Alembic has a cumulative total of 86 ANDA approvals (73 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 <u>http://www.alembicpharmaceuticals.com/</u>; (Reuters: ALEM.NS) (Bloomberg: ALPM) (NSE: APLLTD) (BSE: 533573)

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	영양 중요즘 그는 것 같아요. 눈 옷 상송 등값



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