Alembic
Touching Lives over 100 years

Date: 28th January, 2020

To,
The Manager,
Listing Department
National Stock Exchange of India Ltd.
'Exchange Plaza'
Bandra Kurla Complex, Bandra (E),
Mumbai – 400 051

Dear Sir/Madam,

Sub: Alembic Pharmaceuticals receives USFDA Final Approval for Azithromycin Tablets USP, 600 mg.

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 Azithromycin Tablets USP, 600 mg.

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.

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PRESS RELEASE

28th January, 2020, Vadodara, India

Alembic Pharmaceuticals announces USFDA Final Approval for Azithromycin Tablets USP, 600 mg.

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) Azithromycin Tablets USP, 600 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) Zithromax Tablets, 600 mg, of Pfizer, Inc. (Pfizer). Azithromycin Tablet is a macrolide antibacterial drug indicated for mild to moderate infections caused by designated, susceptible bacteria in acute bacterial exacerbations of chronic bronchitis in adults; acute bacterial sinusitis in adults; uncomplicated skin and skin structure infections in adults; urethritis and cervicitis in adults; genital ulcer disease in men; community-acquired pneumonia in adults and pharyngitis/tonsillitis in adults.

Azithromycin Tablets USP, 600 mg have an estimated market size of US$ 2 million for twelve months ending September 2019 according to IQVIA.

Alembic has a cumulative total of 115 ANDA approvals (103 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 Alembic can be found at http://www.alembicpharmaceuticals.com/; (Reuters: ALEM.NS) (Bloomberg: ALPM) (NSE: APLLTD) (BSE: 533573)

For more information contact:

Ajay Kumar Desai Phone: +91 22 - 306 11681 Email: ajay.desai@alembic.co.in	Mitanshu Shah Phone: +91 265 - 3007630 Email: mitanshu.shah@alembic.co.in

ALEMBIC PHARMACEUTICALS LIMITED VADODARA 390 003