Date: 4th January, 2022

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 Doxycycline Hyclate Delayed-Release Tablets USP, 75 mg, 100 mg, 150 mg, and 200 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 Doxycycline Hyclate Delayed-Release Tablets USP, 75 mg, 100 mg, 150 mg, and 200 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.

PRESS RELEASE

4th January, 2022, Vadodara, India

Alembic Pharmaceuticals receives USFDA Final Approval for Doxycycline Hyclate Delayed-Release Tablets USP, 75 mg, 100 mg, 150 mg, and 200 mg.

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 Doxycycline Hyclate Delayed-Release Tablets USP, 75 mg, 100 mg, 150 mg, and 200 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) Doryx Tablets, 75 mg, 100 mg, 150 mg, and 200 mg, of Mayne Pharma International Pty. Ltd. (Mayne). Doxycycline Hyclate Delayed-Release Tablets are indicated to reduce the development of drug-resistant bacteria and maintain the effectiveness of Doxycycline Hyclate Delayed-Release Tablets and other antibacterial drugs, Doxycycline Hyclate Delayed-Release Tablets should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Doxycycline Hyclate Delayed-Release Tablets USP, 75 mg, 100 mg, 150 mg, and 200 mg have an estimated market size of US$ 10 million for twelve months ending September 2021 according to IQVIA.

Alembic has received year to date (YTD) 16 approvals (12 final approvals and 4 tentative approvals) and a cumulative total of 155 ANDA approvals (135 final approvals and 20 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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