

Date: 15<sup>th</sup> May, 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 Final Approval for Doxycycline Hyclate Tablets USP, 100 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 Tablets USP, 100 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.

**ALEMBIC PHARMACEUTICALS LIMITED**

**PRESS RELEASE**

15<sup>th</sup> May, 2020, Vadodara, India

**Alembic Pharmaceuticals announces USFDA Final Approval for Doxycycline Hyclate Tablets USP, 100 mg.**

Alembic Pharmaceuticals Limited (Alembic) today announced it has received approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Doxycycline Hyclate Tablets USP 100mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) Vibra-Tabs, 100mg of Pfizer, Inc. Doxycycline Hyclate Tablets USP 100mg 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. In acute intestinal amebiasis, doxycycline may be a useful adjunct to amebicides. In severe acne, doxycycline may be useful adjunctive therapy. It is also indicated for the prophylaxis of malaria due to Plasmodium falciparum in short-term travelers (<4 months) to areas with chloroquine and/or primethamine-sulfadoxine resistant strains.

Doxycycline Hyclate Tablets 100mg have an estimated market size of US\$ 53 million for twelve months ending December 2019 according to IQVIA.

Alembic has a cumulative total of 121 ANDA approvals (108 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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**ALEMBIC PHARMACEUTICALS LIMITED**