

Date: 16th October, 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 Approval for Amantadine Hydrochloride Tablets, 100 mg.


With reference to the captioned subject, this is to inform the exchange that the Company has received US Food & Drug Administration (USFDA) Approval for Amantadine Hydrochloride Tablets, 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

REGD. OFFICE : ALEMBIC ROAD, VADODARA - 390 003. • TEL : (0265) 2280550, 2280880 • FAX : (0265) 2281229
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PRESS RELEASE

16th October, 2020, Vadodara, India

Alembic Pharmaceuticals announces USFDA Approval for Amantadine Hydrochloride Tablets, 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) Amantadine Hydrochloride Tablets, 100 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Symmetrel Tablets, 100 mg, of Endo Pharmaceuticals, Inc. (Endo). Amantadine Hydrochloride Tablets are indicated for the prophylaxis and treatment of signs and symptoms of infection caused by various strains of influenza A virus. Amantadine Hydrochloride Tablets are also indicated in the treatment of parkinsonism and drug-induced extrapyramidal reactions.

Amantadine Hydrochloride Tablets, 100 mg have an estimated market size of US\$ 13 million for twelve months ending June, 2020 according to IQVIA.

Alembic has a cumulative total of 132 ANDA approvals (114 final approvals and 18 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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