



Date: 14th November, 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 Cyclophosphamide Capsules, 25 mg and 50 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 Cyclophosphamide Capsules, 25 mg and 50 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

14th November, 2022, Vadodara, India

Alembic Pharmaceuticals receives USFDA Final Approval for Cyclophosphamide Capsules, 25 mg and 50 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 Cyclophosphamide Capsules, 25 mg and 50 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Cyclophosphamide Capsules, 25 mg and 50 mg, of Hikma Pharmaceuticals USA Inc. Cyclophosphamide Capsules is an alkylating drug indicated for the treatment of malignant disease and minimal change nephrotic syndrome in pediatric patients. Refer to our label for full indication.

Cyclophosphamide Capsules, 25 mg and 50 mg, have an estimated market size of US\$ 8 million for twelve months ending Sep 2022 according to IQVIA.

Alembic has a cumulative total of 176 ANDA approvals (152 final approvals and 24 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 <https://www.alembicpharmaceuticals.com/>; (Reuters: ALEM.NS) (Bloomberg: ALPM) (NSE: APLLTD) (BSE: 533573).

For more information contact:

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