

**PRESS RELEASE**

14<sup>th</sup> 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:

Ajay Kumar Desai	Mitanshu Shah
Phone: +91 22 - 306 11681	Phone: +91 265 - 6637630
Email: <a href="mailto:ajay.desai@alembic.co.in">ajay.desai@alembic.co.in</a>	Email: <a href="mailto:mitanshu.shah@alembic.co.in">mitanshu.shah@alembic.co.in</a>



**ALEMBIC PHARMACEUTICALS LIMITED**

REGD. OFFICE : ALEMBIC ROAD, VADODARA - 390 003. • TEL : (0265) 2280550, 2280880 • FAX : (0265) 2281229  
Website : [www.alembicpharmaceuticals.com](http://www.alembicpharmaceuticals.com) • E-mail : [alembic@alembic.co.in](mailto:alembic@alembic.co.in) • CIN : L24230GJ2010PLC061123