

**PRESS RELEASE**

6<sup>th</sup> March, 2023, Vadodara, India

**Alembic Pharmaceuticals announces USFDA Final Approval for Fluorouracil Injection USP, 2.5 g/50 mL (50 mg/mL) Pharmacy Bulk Vial.**

Alembic Pharmaceuticals Limited (Alembic) today announced it has received final approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Fluorouracil Injection USP, 2.5 g/50 mL (50 mg/mL) Pharmacy Bulk Vial. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Fluorouracil Injection, 2.5 g/50 mL (50 mg/mL), of Spectrum Pharmaceuticals, Inc. (Spectrum). Fluorouracil Injection is indicated for the treatment of patients with adenocarcinoma of colon and rectum, adenocarcinoma of the breast, gastric adenocarcinoma and pancreatic adenocarcinoma. Refer to our label for full indication.

Fluorouracil Injection USP, 2.5 g/50 mL (50 mg/mL) Vial, has an estimated market size of US\$ 5 million for twelve months ending Dec 2022 according to IQVIA.

Alembic has a cumulative total of 182 ANDA approvals (159 final approvals and 23 tentative approvals) from USFDA.

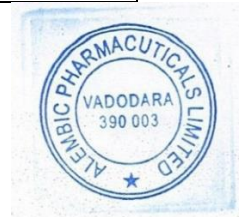
**About Alembic Pharmaceuticals Limited**

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)

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