

## PRESS RELEASE

8<sup>th</sup> July, 2021, Vadodara, India

### **Alembic Pharmaceuticals announces USFDA Final Approval for Desipramine Hydrochloride Tablets USP, 10 mg, 25 mg, 50 mg, 75 mg, 100 mg, and 150 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 Desipramine Hydrochloride Tablets USP, 10 mg, 25 mg, 50 mg, 75 mg, 100 mg, and 150 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Norpramin Tablets, 10 mg, 25 mg, 50 mg, 75 mg, 100 mg, and 150 mg, of Validus Pharmaceuticals LLC. Desipramine Hydrochloride Tablets, USP are indicated for the treatment of depression.

Desipramine Hydrochloride Tablets USP, 10 mg, 25 mg, 50 mg, 75 mg, 100 mg, and 150 mg have an estimated market size of US\$ 7 million for twelve months ending March 2021 according to IQVIA.

Alembic has a cumulative total of 147 ANDA approvals (129 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)

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