PRESS RELEASE

5th August, 2021, Vadodara, India

Alembic Pharmaceuticals announces USFDA Final Approval for Clomipramine Hydrochloride Capsules USP, 25 mg, 50 mg, and 75 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 Clomipramine Hydrochloride Capsules USP, 25 mg, 50 mg, and 75 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Anafranil Capsules, 25 mg, 50 mg, and 75 mg, of SpecGX LLC. Clomipramine Hydrochloride Capsules are indicated for the treatment of obsessions and compulsions in patients with Obsessive-Compulsive Disorder (OCD).

Clomipramine Hydrochloride Capsules USP, 25 mg, 50 mg, and 75 mg, have an estimated market size of US$ 32 million for twelve months ending June 2021 according to IQVIA.

Alembic has a cumulative total of 149 ANDA approvals (131 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: APLLTD) (BSE: 533573)

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