

PRESS RELEASE

29th August, 2022, Vadodara, India

Alembic Pharmaceuticals receives USFDA Final Approval for Chlorthalidone Tablets USP, 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 Chlorthalidone Tablets USP, 25 mg and 50 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Hygroton Tablets, 25 mg and 50 mg, of Sanofi Aventis US LLC (Sanofi). Diuretics such as chlorthalidone are indicated in the management of hypertension either as the sole therapeutic agent or to enhance the effect of other antihypertensive drugs in the more severe forms of hypertension. Chlorthalidone is indicated as adjunctive therapy in edema associated with congestive heart failure, hepatic cirrhosis, and corticosteroid and estrogen therapy. Chlorthalidone has also been found useful in edema due to various forms of renal dysfunction, such as nephrotic syndrome, acute glomerulonephritis, and chronic renal failure.

Chlorthalidone Tablets USP, 25 mg and 50 mg, have an estimated market size of US\$ 37 million for twelve months ending June, 2022 according to IQVIA.

Alembic has a cumulative total of 171 ANDA approvals (147 final approvals and 24 tentative approvals) from USFDA.

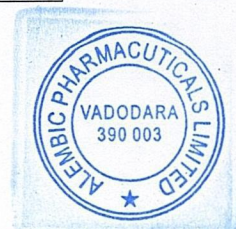
About Alembic Pharmaceuticals Limited

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: ajay.desai@alembic.co.in	Email: mitanshu.shah@alembic.co.in



ALEMBIC PHARMACEUTICALS LIMITED

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