

PRESS RELEASE

13th August, 2019, Vadodara, India

Alembic Pharmaceuticals receives USFDA Approval for Dorzolamide Hydrochloride Ophthalmic Solution USP, 2%.

Alembic Pharmaceuticals Limited today announced that the Company has received approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Dorzolamide Hydrochloride Ophthalmic Solution USP, 2%. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) Trusopt Ophthalmic Solution, 2%, of Merck Sharp & Dohme Corp. Dorzolamide Hydrochloride Ophthalmic Solution is a carbonic anhydrase inhibitor indicated in the treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma.

Dorzolamide Hydrochloride Ophthalmic Solution USP, 2% has an estimated market size of US\$ 35 million for twelve months ending December 2018 according to IQVIA.

Alembic now has a total of 101 ANDA approvals (89 final approvals and 12 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 the company can be found at <http://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 - 3007630
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