



PRESS RELEASE

4th December, 2024, Vadodara, India

Alembic Pharmaceuticals Limited announces USFDA Tentative Approval for Olopatadine Hydrochloride Ophthalmic Solution USP, 0.7% (OTC)

Alembic Pharmaceuticals Limited (Alembic) announced that it has received Tentative Approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Olopatadine Hydrochloride Ophthalmic Solution USP, 0.7% (OTC). The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Pataday Once Daily Relief Ophthalmic Solution, 0.7%, of Alcon Laboratories, Inc. (Alcon) NDA - 206276. Olopatadine Hydrochloride Ophthalmic Solution USP, 0.7% (OTC) is used to temporarily relieve itchy eyes due to pollen, ragweed, grass, animal hair and dander. Refer label for a detailed indication.

Olopatadine Hydrochloride Ophthalmic Solution USP, 0.7% (OTC) has an estimated market size of US\$ 22 million for twelve months ending September 2024 according to IQVIA.

Alembic has a cumulative total of 219 ANDA approvals (192 final approvals and 27 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 field force of over 5200 are well recognized by doctors and patients.

Information about the Company can be found at www.alembicpharmaceuticals.com; (Reuters:ALEM.NS) (Bloomberg:ALPM) (NSE:APLLTD) (BSE:533573)

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