Alembic Pharma Secures USFDA Final Approval for Generic Olopatadine Eye Drops



According to IQVIA, Olopatadine Hydrochloride Ophthalmic Solution USP, 0.7%, had an estimated market size of US$20 million in the United States for twelve months ending September 2026.

This ANDA was developed in collaboration with Orbicular Pharmaceutical Technologies Pvt Ltd.

Alembic has a cumulative total of 248 ANDA approvals (229 final approvals and 19 tentative approvals) from the USFDA.

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 5,800 are well recognized by doctors and patients.

New Delhi: Alembic Pharmaceuticals Limited (Alembic) has announced that it has received final approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application 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, 0.7%, of Alcon Laboratories, Inc. (Alcon). Olopatadine Hydrochloride Ophthalmic Solution USP, 0.7%, is indicated for the temporary relief of itchy eyes due to pollen, ragweed, grass, animal hair and dander. Refer label for a detailed indication and usage.

News Source:

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