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Alembic gets USFDA nod for Olopatadine Hydrochloride Ophthalmic Solution

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Olopatadine Hydrochloride Ophthalmic Solution USP, 0.2% is indicated for the treatment of ocular itching associated with allergic conjunctivitis

Alembic Pharmaceuticals Limited recently announced that the Company has received approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Olopatadine Hydrochloride Ophthalmic Solution USP, 0.2%.

The approved ANDA is therapeutically equivalent to the reference listed drug (RLD), Pataday Ophthalmic Solution, 0.2%, of Novartis Pharmaceuticals Corporation. Olopatadine Hydrochloride Ophthalmic Solution USP, 0.2% is indicated for the treatment of ocular itching associated with allergic conjunctivitis.

Olopatadine Hydrochloride Ophthalmic Solution USP, 0.2% has an estimated market size of US$ 62 million for twelve months ending December 2018 according to IQVIA. Alembic now has a total of 93 ANDA approvals (81 final approvals and 12 tentative approvals) from USFDA.