

Alembic Pharma set to launch allergic conjunctivitis drug

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Alembic Pharmaceuticals Limited has received approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Azelastine Hydrochloride Ophthalmic Solution, 0.05%.

The approved ANDA is therapeutically equivalent to the reference listed drug (RLD), Optivar Ophthalmic Solution, 0.05%, of Mylan Specialty L.P. (Mylan). Azelastine Hydrochloride Ophthalmic Solution 0.05% is indicated for the treatment of itching of the eye associated with allergic conjunctivitis.

Azelastine Hydrochloride Ophthalmic Solution, 0.05%, has an estimated market size of US\$ 8.5 million for twelve months ending December 2018 according to IQVIA. Alembic now has a total of 89 ANDA approvals (76 final approvals and 13 tentative approvals) from USFDA.