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Alembic Pharma gets USFDA nod for Moxifloxacin Ophthalmic Solution

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Moxifloxacin Ophthalmic Solution USP, 0.5% is indicated for the treatment of bacterial conjunctivitis caused by susceptible strains of certain organisms.

Alembic Pharmaceuticals Limited (Alembic) announced that it has received approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Moxifloxacin Ophthalmic Solution USP, 0.5%. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) Vigamox Ophthalmic Solution USP, 0.5%, of Novartis Pharmaceuticals Corporation. Moxifloxacin Ophthalmic Solution USP, 0.5% is indicated for the treatment of bacterial conjunctivitis caused by susceptible strains of certain organisms.

Moxifloxacin Ophthalmic Solution USP, 0.5% has an estimated market size of US$ 68 million for twelve months ending December 2018 according to IQVIA.

Alembic has a cumulative total of 86 ANDA approvals (73 final approvals and 13 tentative approvals) from USFDA.