BioSpectrum the business of Bio & Health Sciences

Alembic Pharma set to treat benign prostatic hyperplasia

26 November 2019 | News

Alembic Pharmaceuticals receives USFDA Final Approval for Silodosin Capsules, 4 mg and 8 mg

Alembic Pharmaceuticals Limited has received final approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Silodosin Capsules, 4 mg and 8 mg.

The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Rapaflo Capsules, 4 mg and 8 mg, of Allergan Sales, LLC. Silodosin capsule, a selective alpha1 adrenergic receptor antagonist, is indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH).

Silodosin Capsules have an estimated market size of US$ 114 million for twelve months ending June 2019 according to IQVIA. Alembic now has a total of 108 ANDA approvals (96 final approvals and 12 tentative approvals) from USFDA.