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Alembic receives USFDA approval for depression drug

16 January 2020 | News

Alembic gets USFDA nod for Vilazodone Hydrochloride Tablets, which are indicated for the treatment of major depressive disorder

Alembic Pharmaceuticals Limited (Alembic) has announced that the Company has received final approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Vilazodone Hydrochloride Tablets, 10 mg, 20 mg, and 40 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Viibryd Tablets, 10 mg, 20 mg, and 40 mg, of Allergan Sales, LLC (Allergan). Vilazodone Hydrochloride Tablets are indicated for the treatment of major depressive disorder.

Vilazodone Hydrochloride Tablets, 1 O mg, 20 mg, and 40 mg have an estimated market size of US$ 469 million for twelve months ending September 2019 according to IQVIA. Alembic had previously received tentative approval for this ANDA. Alembic was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification and hence is eligible for 180 days of shared exclusivity. The launch of this product will be as per settlement agreement with Allergan.

Alembic has a cumulative total of 110 ANDA approvals (98 final approvals and 12 tentative approvals) from USFDA.