BioSpectrum
the business of Bio & Health Sciences

Alembic Pharma gets USFDA nod for hypertension drug

05 December 2018 | News

Drug firm Alembic Pharmaceuticals has said that it has received approval from the US health regulator for Candesartan Cilexetil tablets, used for treatment of hypertension.

Alembic Pharmaceuticals Limited has announced that the Company has received approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Candesartan Cilexetil Tablets USP, 4 mg, 8 mg, and 16 mg.

The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Atacand Tablets, 4 mg, 8 mg, and 16 mg, of ANI Pharmaceuticals, Irie. Candesartan cilexetil tablets are indicated for the treatment of hypertension in adults and in children 1 to <17 years of age to lower blood pressure. Candesartan cilexetil tablets also indicated for the treatment of heart failure.

Candesartan Cilexetil Tablets USP, 4 mg, 8 mg, and 16 mg, hzve an estimated market size of $ 22 million for twelve months ending December 2017 according to IQVIA. Alembic has a cumulative total of 82 ANDA approvals (69 final approvals and 13 tentative approvals) from USFDA.