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Alembic Pharma receives USFDA approval for diabetes drug

16 October 2018 | News

The company has received tentative approval from the US Food and Drug Administration (USFDA) for its Alogliptin tablets in the strengths of 6.25 mg, 12.5 mg and 25mg.

Drug firm Alembic Pharmaceuticals has received tentative nod from the US health regulator for its Alogliptin tablets used for treatment of type 2 diabetes.

The company has received tentative approval from the US Food and Drug Administration (USFDA) for its Alogliptin tablets in the strengths of 6.25 mg, 12.5 mg and 25mg, Alembic Pharma said in a BSE filing.

The product is generic version of Takeda Pharms USA's Nesina tablets in the same strengths.

The tablets are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus, Alembic Pharma said.

"Alogliptin tablets, 6.25 mg, 12.5 mg and 25mg has an estimated market size of USD 65.6 million for twelve months ending December 2017 according to IQVIA," it added.

The company now has a total of 78 abbreviated new drug application (ANDA) approvals (64 final approvals and 14 tentative approvals) from USFDA, Alembic Pharma said.