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Alembic Pharma gets USFDA nod for Parkinson's treatment drug

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The approved product is a therapeutic equivalent to the reference listed drug product (RLD) Mirapex ER tablets, of Boehringer Ingelheim Pharmaceuticals Inc.

Drug firm Alembic Pharmaceuticals has said that it has received approval from the US health regulator for Pramipexole Dihydrochloride extended-release tablets used for the treatment of Parkinson's disease.

The approval from the United States Food and Drug Administration is for the company's abbreviated new drug application (ANDA) for Pramipexole Dihydrochloride extended-release tablets, in the strengths of 0.375 mg, 0.75 mg, 1.5 mg, 2.25 mg, 3 mg, 3.75 mg, and 4.5 mg, Alembic Pharmaceuticals said in a filing to BSE.

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Quoting IQVIA data, Alembic Pharma said Pramipexole Dihydrochloride extended-release tablets have an estimated market size of USD 38.6 million for twelve months ending December 2017.

The company currently has a total of 84 ANDA approvals (71 final approvals and 13 tentative approvals) from USFDA, it added.