Alembic gets USFDA approval for generic chronic constipation treatment tablets

Citing IQVIA data, the company said prucalopride tablets, 1 mg and 2 mg, had an estimated market size of USD 100 million for 12 months ended March 2026.

New Delhi: Alembic Pharmaceuticals has received final approval from the US health regulator for its generic version of prucalopride tablets indicated for the treatment of chronic idiopathic constipation in adults.

The final approval granted by the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) prucalopride tablets of strengths 1 mg and 2 mg, Alembic said in a statement.

The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Motegrity tablets, 1 mg and 2 mg, of Takeda Pharmaceuticals USA Inc, it added.

Prucalopride tablets are indicated for the treatment of chronic idiopathic constipation (CIC) in adults.

Citing IQVIA data, the company said prucalopride tablets, 1 mg and 2 mg, had an estimated market size of USD 100 million for 12 months ended March 2026.

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