

Aurobindo Pharma gets USFDA nod for generic glycerol phenylbutyrate oral liquid

The final approval granted by the US Food & Drug Administration (USFDA) is to manufacture and market glycerol phenylbutyrate oral liquid of strength 1.1 gram per ml, Aurobindo Pharma said in a regulatory filing.



New Delhi: Aurobindo Pharma Ltd on Friday said it has received final approval from the US health regulator to manufacture and market its generic version of glycerol

phenylbutyrate oral liquid indicated to lower high levels of ammonia in blood caused by urea cycle disorders.

The final approval granted by the US Food & Drug Administration (USFDA) is to manufacture and market glycerol phenylbutyrate oral liquid of strength 1.1 gram per ml, Aurobindo Pharma said in a regulatory filing.

It is bioequivalent and therapeutically equivalent to the reference listed drug Ravicti oral liquid 1.1 gram per ml of Horizon Therapeutics US Holding LLC, it added.

Glycerol phenylbutyrate oral liquid is indicated for use as a nitrogen-binding agent for chronic management of patients with urea cycle disorders (UCDs), who cannot be managed by dietary protein restriction and/or amino acid supplementation alone, Aurobindo Pharma said.

The product will be manufactured by Unit-III of the company and will be launched immediately, it added.

Citing IQVIA MAT data, the company said the approved product has an estimated market size of \$50.2 million for the 12 months ended February 2026.

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