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Aurobindo Pharma to market Potassium Chloride ER Tablets

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The product will be launched in January 2019

Aurobindo Pharma Limited is pleased to announce that the company has received final approval from the US Food & Drug Administration (USFDA) to manufacture and market Potassium Chloride Extended Release tablets, 8 mEq (600 mg) and 10 mEq (750 mg).

Potassium Chloride Extended-Release tablets, a generic version of Upsher-Smith's Klor-Con® Extended Release tablets. The product will be launched in January 2019. Potassium Chloride tablets are indicated for the treatment of hypokalemia, with or without metabolic alkalosis, in digitalis intoxication, and in hypokalemic familial periodic paralysis.

The approved product has an estimated market size of ~US$ 60 million for the twelve months ending October 2018, according to IQVIA.

This is the 5 th ANDA (including 2 tentative approvals) to be approved out of Unit X formulation facility in Naidupet, India used for manufacturing oral products. Aurobindo now has a total of 396 ANDA approvals (368 Final approvals including 20 from Aurolife Pharma LLC and 28 tentative approvals) from USFDA.