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Aurobindo Pharma gets FDA nod for new generic

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Aurobindo Pharma Limited is pleased to announce that the company has received final approval from the US Food and Drug Administration (US FDA) to manufacture and market Sildenafil Tablets, 20 mg (ANDA 203963). This product is expected to be launched by Q4 FY 2015-16.]

The approved ANDA is bioequivalent and therapeutically equivalent to the reference listed drug product (RLD) REVATIO sildenafil citrate) Tablets 20 mg of Pfizer.

Sildenafil Tablets are used in the treatment of pulmonary arterial hypertension (high blood pressure in the lungs). The approved product has an estimated market size of $80 million for the twelve months ending September 2015 according to IMS.