

Aurobindo gains FDA approval for fungal infections tablets

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Aurobindo Pharma is pleased to announce that the company has received final approval from the US Food and Drug Administration (USFDA) to manufacture and market Voriconazole Tablets, 50 mg and 200 mg. This product is expected to be launched in Q4 FY15-16.

The approved ANDA is bioequivalent and therapeutically equivalent to the reference listed drug product (RLD) VFEND Tablets, 50 mg and 200 mg of PF Prism CV(Prism).

Voriconazole Tablets is used in the treatment of fungal infections for patients 12 years of age and older. The approved product has an estimated market size of \$103 million for the twelve months ending November 2015 according to IMS.

This is the 59th ANDA to be approved out of Aurobindo's Unit VII formulation facility in Hyderabad, India for manufacturing Oral Non-Antibiotic products.