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Aurobindo Pharma receives FDA approval for antibiotic drug

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Aurobindo Pharma has announced that the company has received final approval from the US Food and Drug Administration (USFDA) to manufacture and market Vancomycin Hydrochloride for Injection USP, 5 g/vial and 10 g/vial (Pharmacy Bulk Package). This product is expected to be launched in the later part of FY16-17.

The approved ANDA is bioequivalent and therapeutically equivalent to the reference listed drug product (RLD) Vancomycin Hydrochloride for Injection USP, 5 g/vial and 10 g/vial (Pharmacy Bulk Package), of Fresenius Kabi USA, LLC.

Vancomycin Hydrochloride for Injection is an antibiotic used in the treatment of severe infections caused by susceptible strains of methicillin-resistant (Beta-lactam resistant) staphylococci and others. The approved product has an estimated market size of $160 million for the twelve months ending January 2016 according to IMS.