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Aurobindo Pharma wins FDA approval for new generic

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Aurobindo Pharma has received final approval from the US Food and Drug Administration (USFDA) to manufacture and market Acetylcysteine Injection, 6g/30 mL (200 mg/mL) single-dose vials. The product is expected to be launched in Q1 FY16-17.

The approved ANDA is bioequivalent and therapeutically equivalent to the reference listed drug product (RLD) Acetadote Injection, 6 g/30 mL, of Cumberland Pharmaceuticals.

Acetylcysteine Injection is an antidote for acetaminophen (non-aspirin pain reliever or analgesic) overdose indicated to prevent or lessen hepatic injury after ingestion of a potentially hepatotoxic quantity of acetaminophen.

The approved product has an estimated market size of $28 million for the twelve months ending December 2015 according to IMS.