

FDA nod for Aurobindo Pharma's dementia drug

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Aurobindo Pharma is pleased to announce that the company has received the final approval from the US Food and Drug Administration (US FDA) to manufacture and market Memantine Hydrochloride Tablets, 5mg and 10mg (ANDA 203175). This approval is an extension of tentative approval received on 24 March 2014. The product is ready for launch.

The approved ANDA is bioequivalent and therapeutically equivalent to the reference listed drug product (RLD) NAMENDA 5mg and 10mg of Forest Laboratories.

Memantine Hydrochloride Tablets are used for the treatment of moderate to severe dementia of the Alzheimer's type. The approved product has an estimated market size of \$1.23 billion for the twelve months ending August 2015 according to IMS.