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FDA nod to Aurobindo's new drug

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Aurobindo Pharma has announced that the company has received final approval from the US Food and Drug Administration (US FDA) to manufacture and market Flecainide Acetate Tablets USP 50 mg, 100 mg and 150 mg (ANDA 202821). The company will commence shipping shortly.

The approved ANDA is bioequivalent and therapeutically equivalent to the reference listed drug product (RLD) Tambocor Tablets, 50 mg, 100 mg, 150 mg.

Flecainide Acetate Tablets are an antiarrhythmic agent with an estimated market size of $61 million for the twelve months ending April 2015, according to IMS.

This is the 40th ANDA to be approved out of Unit VII formulation facility in Hyderabad, for manufacturing Oral Non-betalactam products, said the company.