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FDA nod for Aurobindo's anti-psychotic tablets

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Aurobindo Pharma has announced that the company has received the final approval from the US Food and Drug Administration (US FDA) to manufacture and market
Aripiprazole Tablets, 2mg, 5mg, 10mg, 15mg, 20mg and 30mg (ANDA 203908). The product is ready for launch.

The approved ANDA is bioequivalent and therapeutically equivalent to the reference listed drug product (RLD) Abilify Tablets 2mg, 5mg, 10mg, 15mg, 20mg and 30mg of Otsuka Pharmaceutical Company (Otsuka).

Aripiprazole Tablets are a typical anti-psychotic indicated in the treatment symptoms of psychotic conditions such as schizophrenia and bipolar disorder (manic depression). The approved product has an estimated market size of $7.3 Billion for the twelve months ending August 2015, according to IMS.

This is the 48th ANDA to be approved out of Unit VII formulation facility in Hyderabad, India for manufacturing Oral Non-Antibiotic products. Aurobindo now has a total of 215 ANDA approvals (187 Final approvals including 10 from Aurolife Pharma and 28 Tentative approvals) from the US FDA.