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Aurobindo gets FDA nod for anti-depression generic

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FDA approves Aurobindo's Escitalopram Oxalate Tablets



Singapore: India's Aurobindo Pharma received final approval from the US FDA to manufacture and market Escitalopram Oxalate tablets 5mg, 10mg and 20mg (ANDA 090432), which was earlier tentatively approved.

Escitalopram Oxalate tablets 5mg, 10mg and 20mg are the generic equivalent of Forest Laboratories' Lexapro tablets 5mg, 10mg and 20mg, used as anti-depressant and falls under the Central Nervous System (CNS) segment.

It is indicated for treatment of depression associated with mood disorders and has a market size of approximately $2.8 billion for the 12 months ending March 2012, according to IMS.

The product has been approved out of unit III formulations facility in Hyderabad, India. Aurobindo now has a total of 158 ANDA approvals (133 final approvals including one from Aurolife Pharma and 25 tentative approvals) from the US FDA.