



3<sup>rd</sup> June 2014

### **Aurobindo Pharma receives USFDA Approval for Divalproex Sodium Extended-Release Tablets**

Aurobindo Pharma Limited is pleased to announce that the company has received final approval from the US Food & Drug Administration (USFDA) to manufacture and market Divalproex Sodium Extended-release Tablets USP 250mg and 500mg. (ANDA 202419). The product is ready for launch.

Divalproex Sodium Extended-release Tablets USP 250mg and 500mg is the generic equivalent of AbbVie Inc's Depakote® ER Extended-release Tablets, 250mg and 500mg respectively and indicated for the treatment of acute manic or mixed episodes associated with bipolar disorder, with or without psychotic features. The product has a market size of approximately US\$ 690 Million for the twelve months ending March 2014 according to IMS.

This ANDAs has been approved out of Unit VII (SEZ) formulation facility in Hyderabad, India

Aurobindo now has a total of 194 ANDA approvals (168 Final approvals including 7 from Aurolife Pharma LLC and 26 Tentative approvals) from USFDA

#### **About Aurobindo Pharma Limited:**

Aurobindo Pharma Limited ([www.aurobindo.com](http://www.aurobindo.com)), headquartered at Hyderabad, India, manufactures generic pharmaceuticals and active pharmaceutical ingredients. The company's manufacturing facilities are approved by several leading regulatory agencies like US FDA, UK MHRA, Japan PMDA, WHO, Health Canada, MCC South Africa, ANVISA Brazil. The company's robust product portfolio is spread over 6 major therapeutic/product areas encompassing Antibiotics, Anti-Retrovirals, CVS, CNS, Gastroenterologicals, and Anti-Allergics, supported by an outstanding R&D set-up. The Company is marketing these products globally, in over 125 countries.

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