



16th September 2014

Aurobindo Pharma receives USFDA Approval for Amoxicillin for Oral Suspension

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 Amoxicillin for Oral Suspension USP 125mg/5mL and 250mg/5mL (ANDA 204030).

Amoxicillin for Oral Suspension USP 125mg/5mL and 250mg/5mL is the generic equivalent to the reference listed drug product (RLD), Amoxicillin for Oral Suspension, 125mg/5 mL and 250mg/5mL respectively of Teva Pharmaceutical Industries Ltd and indicated in the treatment of infections due to susceptible β lactamase-negative strains of the designated microorganisms. The product has a market size of approximately US\$ 19 Million for the twelve months ending July 2014 according to IMS.

This ANDAs has been approved out of Unit XII, Semi-Synthetic Penicillin (SSP) formulation facility in Hyderabad, India

Aurobindo now has a total of 195 ANDA approvals (169 Final approvals including 7 from Aurolife Pharma LLC and 26 Tentative approvals) from USFDA

About Aurobindo Pharma Limited:

Aurobindo Pharma Limited (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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