



15th June 2015

Aurobindo Pharma receives USFDA Approval for Extended Phenytoin Sodium Capsules

Aurobindo Pharma Limited is pleased to announce that the company has received the final approval from the US Food & Drug Administration (USFDA) to manufacture and market Extended Phenytoin Sodium Capsules USP, 100mg (ANDA 204309).

The approved ANDA is bioequivalent and therapeutically equivalent to the reference listed drug product (RLD) Dilantin® of Parke-Davis Division of Pfizer Inc.

Phenytoin Sodium Extended Capsules is an anti-epileptic product and indicated for the control of seizures and prevention and treatment of seizures occurring during or following neurosurgery. The product has an estimated market size of US\$125 Million for the twelve months ending April 2015 according to IMS.

This is the 38th ANDA to be approved out of Unit VII formulation facility in Hyderabad, India for manufacturing Oral Non-betalactam products. Aurobindo now has a total of 199 ANDA approvals (172 Final approvals including 9 from Aurolife Pharma LLC and 27 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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