22nd June 2015

Aurobindo Pharma receives USFDA Approval for Entacapone Tablets

Aurobindo Pharma Limited is pleased to announce that the company has received final approvals from the US Food & Drug Administration (USFDA) to manufacture and market Entacapone Tablets USP, 200mg (ANDA 203437). The product will be launched soon.

The approved ANDA is bioequivalent and therapeutically equivalent to the reference listed drug product (RLD) Comtan® Tablets 200mg of Orion Corporation. Entacapone Tablets are used in the treatment of Parkinson's disease and has an estimated market size of US$59 Million for the twelve months ending April 2015 according to IMS.

This is the 39th ANDA to be approved out of Unit VII formulation facility in Hyderabad, India for manufacturing Oral Non-betalactam products.

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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