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Aurobindo Pharma receives USFDA Approval for Metronidazole Tablets USP

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 Metronidazole Tablets USP 250mg and 500mg (ANDA 203974). Aurobindo will commence shipping shortly.

The approved ANDA is bioequivalent and therapeutically equivalent to the reference listed drug product (RLD) Flagyl® Tablets, 250mg and 500mg of GD Searle LLC.

Metronidazole Tablets are used to treat different types of infections which are due to particular types of bacteria and some other infectious organisms, or to prevent infection during an operation. The product has an estimated market size of US\$58 Million for the twelve months ending March 2015 according to IMS.

This is the 37th 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 194 ANDA approvals (167 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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