20th August 2015

# Aurobindo Pharma receives USFDA Approval for Omeprazole Delayed-release 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 Omeprazole Delayed-release Capsules USP, 10mg, 20mg and 40mg (ANDA 203270).

The approved ANDA is bioequivalent and therapeutically equivalent to the reference listed drug product (RLD) Prilosec® Delayed-release Capsules, 10mg, 20mg and 40mg of AstraZeneca Pharmaceuticals.

Omeprazole Delayed-release Capsules are indicated for short-term treatment of active duodenal ulcer in adults. The product has an estimated market size of US$422 Million for the twelve months ending June 2015 according to IMS.

This is the 43rd 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 208 ANDA approvals (180 Final approvals including 9 from Aurolife Pharma LLC and 28 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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