

9th April 2015

Aurobindo Pharma receives USFDA Approval for Atracurium Besylate Injections

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 Atracurium Besylate Injection, 10mg/mL, 5mL single-dose vials (ANDA 206010) and 10mg/mL, 10mL multi-dose vials (ANDA 206011).

The approved ANDAs are bioequivalent and therapeutically equivalent to the reference listed drug product (RLD) Atracurium Besylate Injections USP of Eurohealth International Sarl. Atracurium Besylate Injections are indicated as an adjunct to general anesthesia, to facilitate endotracheal intubation and to provide skeletal muscle relaxation during surgery or mechanical ventilation

Aurobindo now has 11 ANDAs (represented by 8 product classes) approved out of Unit IV formulation facility in Hyderabad, India for manufacturing general injectable products and will be marketed and sold by Aurobindo's wholly owned subsidiary AuroMedics Pharma LLC

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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