27th July 2015

Aurobindo Pharma receives USFDA Approval for Esmolol Hydrochloride Injection

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 Esmolol Hydrochloride Injection, 100mg/10mL (10mg/mL), (ANDA 205520).

Esmolol Hydrochloride Injection, 100mg/10mL (10mg/mL) is bioequivalent and therapeutically equivalent to the reference listed drug product (RLD) Brevibloc® Injection, 10mg/mL of Baxter Healthcare Corporation. Esmolol Hydrochloride Injection is indicated for the short-term treatment of tachycardia and hypertension that occur during induction and tracheal intubation, during surgery, on emergence from anesthesia and in the postoperative period.

Aurobindo now has 13 ANDAs (represented by 10 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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