

NEWS RELEASE

18th March 2016, Hyderabad, India

Aurobindo Pharma receives USFDA Approval for Dexmedetomidine Hydrochloride Injection

Aurobindo Pharma Limited is pleased to announce that the company has received final approval from the US Food & Drug Administration (USFDA) to manufacture and market Dexmedetomidine Hydrochloride Injection, 200 mcg (base)/2 mL (100 mcg (base)/mL) single-dose vials. The product is to be launched post Q1 FY16-17.

The approved ANDA is bioequivalent and therapeutically equivalent to the reference listed drug product (RLD) Precedex[®] Injection, 200 mcg/2 mL, of Hospira, Inc.

Dexmedetomidine Hydrochloride Injection is used as a sedation of non-intubated patients prior to and/or during surgical and other procedures. The approved product has an estimated market size of \$59.1 million for the twelve months ending January 2016 according to IMS.

This is the 27th ANDA (including two tentative approvals) to be approved out of Unit IV formulation facility in Hyderabad, India used for manufacturing general injectable products. Aurobindo now has a total of 244 ANDA approvals (209 Final approvals including 10 from Aurolife Pharma LLC and 35 tentative approvals) from USFDA.

About Aurobindo Pharma Limited:

Aurobindo Pharma Limited (www.aurobindo.com) (NSE: AUROPHARMA, BSE: 524804, Reuters: ARBN.NS, Bloomberg: ARBP:IN), 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-Allergies, supported by an outstanding R&D set-up. The Company is marketing these products globally, in over 150 countries.

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Disclaimer:

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