15th April 2015

Aurobindo Pharma receives USFDA Approval for Cefixime for Oral Suspension 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 Cefixime for Oral Suspension USP, 100mg/5mL and 200mg/5mL (ANDA 204835). The product is ready for launch.

The approved ANDAs are bioequivalent and therapeutically equivalent to the reference listed drug product (RLD) Suprax® Oral Suspension USP 100mg/5mL and 200mg/5mL respectively of Lupin Pharmaceuticals Inc.

Cefixime for Oral Suspension is indicated for the treatment of adults and pediatric patients six months of age or older, with infections caused by susceptible strains of the designated organisms in urinary tract infections, otitis media, acute exacerbations of chronic bronchitis, uncomplicated gonorrhea (cervical/urethral), pharyngitis and tonsillitis

The product has an estimated market size of US$ 123 Million for the twelve months ending February 2015 according to IMS.

Aurobindo now has 11 ANDAs (represented by 7 product classes) approved out of Unit VI formulation facility in Hyderabad, India for manufacturing Oral Cephalosporin products.

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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