



26th April 2013

Aurobindo Pharma receives USFDA Approval for Cefadroxil Oral Suspension

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 Cefadroxil for Oral Suspension USP 250mg/5mL and 500mg/5mL (ANDA 065349).

Cefadroxil for Oral Suspension USP, 250mg/5mL and 500mg/5mL is the generic equivalents of Warner Chilcott Company, Inc's Duricef® for Oral Suspension 250mg/5mL and 500mg/5mL. Cefadroxil for Oral Suspension is a cephalosporin antibiotic indicated for the treatment of patients with infection caused by susceptible strains of the designated organisms such as urinary tract infections caused by E.coli, P.mirabilis, and Klebsiella species; skin and skin structure infections caused by staphylococci and/or streptococci; Pharyngitis and/or tonsillitis caused by Streptococcus pyogenes.

The product has been approved out of Unit VI Cephalosporin formulations manufacturing facility in Hyderabad, India

Aurobindo now has a total of 187 ANDA approvals (160 Final approvals including 4 from Aurolife Pharma LLC and 27 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, 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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