Aurobindo Pharma receives tentative approval for its New Drug Application (NDA)

Efavirenz Tablets 100mg

Aurobindo Pharma Limited is pleased to announce that it has received the tentative approval to manufacture and market Efavirenz Tablets 100mg from the US Food & Drug Administration (USFDA).

The New Drug Application (NDA) 22-297 provides for the use of Efavirenz Tablets 100mg in combination with other antiretrovirals agents and is indicated for the treatment of HIV infections.

The company had earlier received tentative approvals to Efavirenz Tablets 600mg, Efavirenz Capsules 50, 100 and 200 mg and Co-Packaged Lamivudine / Zidovudine Tablets & Efavirenz Tablet 150 mg / 300 mg & 600 mg

This is Aurobindo's 86th ANDA approval from USFDA (61 Final approvals, 25 Tentative approvals).

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 100 countries..

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