PRESS INFORMATION BUREAU
पत्र सूचना कार्यालय
GOVERNMENT OF INDIA
भारत सरकार

Business L ne, Delhi
Monday 23rd November 2015, Page: 18
Width: 13.50 cn , Height: 5.41 cms, a4, Ref: pmin.2015-11-23.45 103

US clears Aurobi ndo drug to treat high BP

OUR BUREAU
Hyderabad, November 22

Aurobindo Pharma has announced that the company has received final approval from the US Food & Drug Administration (USFDA) to manufacture and market Sildenafil tablets, 20 mg.

This product is expected to be launched by Q4 FY 2015-16. The approved ANDA is bioequivalent and therapeutically equivalent to the reference listed drug product REVATIO (sildenafil citrate) tablets of 20 mg of Pfizer, Inc, Aurobindo informed the BSE.

Sildenafil tablets are used in the treatment of pulmonary arterial hypertension (high blood pressure in the lungs). The approved product has an estimated market size of $80 million for the 12 months ended September 2015.

This is the 51st ANDA to be approved out of Unit VII formulation facility in Hyderabad for manufacture of oral non-antibiotic products. Aurobindo now has a total of 219 ANDA approvals (190 final approvals, including 10 from Aurolife Pharma LLC and 29 tentative approvals) from the USFDA.

Company