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Aurobindo Pharma receives final approval for Metformin Hydrochloride Extended Release Tablets

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 Metformin Hydrochloride Extended-Release (ER) Tablets USP 500mg and 750mg. (ANDA 079118). The product is ready for launch.

Metformin Hydrochloride ER Tablets USP 500mg and 750mg is the generic equivalent of Bristol Myers Squibb Company (BMS)'s Glucophage XR® Extended-release Tablets 500mg and 750mg respectively. Metformin Hydrochloride ER Tablets are oral anti-hyperglycemic drugs indicated as an adjunct to diet and exercise to improve glycemic control in patients with type-2 diabetes. The annual sale of the product is approximately US$ 230 million.

The product has been approved out of Unit III formulations facility in Hyderabad, India

Aurobindo now has a total of 153 ANDA approvals (127 Final approvals including 1 from Aurolife Pharma LLC and 26 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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