

URGENT
PRESS RELEASE



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Wockhardt receives US FDA approval for antibacterial Levofloxacin

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Pharmaceutical and biotechnology major Wockhardt has received tentative approval from the United States Food & Drug Administration (US FDA) for marketing the 250mg, 500mg and 750mg tablets of Levofloxacin, which is used for treatment in a broad spectrum of bacterial infections. Levofloxacin is the generic name for the brand Levaquin, marketed in the United States by Ortho Mcneil (Johnson & Johnson). Wockhardt will launch the product immediately upon expiration of the patent on June 20, 2011. Levofloxacin is a very widely used antibacterial drug and belongs to the fluoroquinolone group. According to IMS, the total market for Levofloxacin tablets in the US is about \$1.6 billion.

“Ability to launch products on the date of patent expiration is the most critical element of success in the highly competitive US generics market,” said Wockhardt Chairman Habil Khorakiwala. “Receiving the tentative approval will enable Wockhardt to plan a successful launch of Levofloxacin in the US. We have had a good start to the year 2010, with two tentative approvals in as many weeks,” he further added.

In the US generic pharmaceutical market, Wockhardt has been consistently growing market shares for all its products. In many instances, Wockhardt, by virtue of being amongst the first to market, will gain advantages of being an early entrant.

The Levofloxacin tablets will be manufactured at the US FDA certified formulation plant at Waluj, Aurangabad. The tablets were developed in-house.

About Wockhardt

Wockhardt is a technology-driven global pharmaceutical and biotechnology major with an innovative multi-disciplinary research and development programme. It has 5 research centres and 14 world-class manufacturing plants dotting various countries and continents that are compliant to international regulatory standards such as the US FDA, MHRA and other global regulatory bodies. It has end-to-end integrated capabilities for its products, starting with manufacture of the oral and sterile API's, the dosage forms and marketing through its wholly owned subsidiary in the US. Wockhardt has a global footprint including the US, UK, Ireland and France with a multi-ethnic workforce from 14 different nationalities.

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