BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

# Wockhardt gets FDA nod for epilepsy generic

09 January 2013 | News | By BioSpectrum Bureau

**Wockhardt gets green signal from FDA for epilepsy drug Lamictal XR**


**Mumbai:** Pharmaceutical and biotechnology major, Wockhardt, has received final approval from the US FDA for marketing 25 mg, 50 mg, 100 mg, 200 mg and 300 mg extended release tablets of Lamotrigine, which is used in treatment of epilepsy. Lamotrigine is the generic name for the brand Lamictal XR, marketed in the US by GlaxoSmithKline. Wockhardt is launching the product immediately and this will be amongst the earliest generic versions of this product in the market.

"We are continuing our rapid momentum of 2012 into the New Year with this approval of Lamotrigine extended release tablets," said Dr Habil Khorakiwala , Wockhardt founder chairman and group CEO. "This is the sixth product with drug delivery technology that has received US FDA approval in the last five months, a continuing testimony to the R&D capabilities of Wockhardt," he said.

According to IMS Health, the total market for this product in the US is about $250 million. Lamotrigine is used extensively in management of epilepsy. Wockhardt already markets several other products in the US in the central nervous system (CNS) segment, especially anti-convulsant drugs.

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 few players to market technically challenging products has reaped the advantage of being an early entrant.

Wockhardt will be manufacturing the extended-release tablets of Lamotrigine at its facility in Aurangabad, India. The technology for the extended release tablets was developed in-house.