



## **Wockhardt receives tentative US FDA approval for generic version of depression drug Cymbalta®**

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Pharmaceutical and biotechnology major Wockhardt has received tentative approval from the United States Food & Drug Administration (US FDA) for marketing 20mg, 30mg and 60mg delayed release capsules of Duloxetine hydrochloride which is used in treatment of depression. Duloxetine is the generic name for the brand Cymbalta®, marketed in the United States by Eli Lilly and Company. The patent covering this product is under litigation in the US courts and Wockhardt will launch the product after resolution of the same. According to IMS Health, the total market for this product in the US is about \$3.3 billion.

“Wockhardt was amongst the first-to-file companies with a paragraph-IV certification for Duloxetine DR capsules” said Wockhardt Chairman Habil Khorakiwala. “We will now be amongst the first-to-market this product, as and when the generic market opens up. Wockhardt plans to sustain its rapid growth in the US market through a series of such first-to-market launches”, he commented further.

Duloxetine is amongst the most widely used drugs in treating depression and generalized anxiety disorder.

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, has reaped the advantage of being an early entrant.

Wockhardt will be manufacturing the Duloxetine HCl API at its FDA approved facility in Ankleshwar, Gujarat and the capsules at its facility in Aurangabad. The technology for the API as well as for the delayed release capsules was developed in-house.

Wockhardt is one of the few companies with end-to-end integrated capabilities for its products, starting with manufacture of the oral and sterile API's, the dose forms and marketing through the wholly-owned subsidiary in the US, enabling the company to capture maximum value.

### **About Wockhardt**

Wockhardt is a high technology global pharmaceuticals and biotechnology major with innovative multi-disciplinary research and development programmes. It has 5 research centres and 21 world-class manufacturing plants in India, USA, UK, France and Ireland. Wockhardt has a multi-ethnic workforce of over 6500 people from 14 different nationalities.