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**PRESS RELEASE**



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## **Wockhardt to launch Divalproex ER in the US market**

### **Gets US FDA approval for generic version of epilepsy drug**

**Mumbai, February 11, 2009**

Pharmaceutical and biotechnology major Wockhardt will be launching Divalproex sodium extended tablets in the United States. Wockhardt received the final approval from the United States Food & Drug Administration (US FDA) for marketing the ER tablets containing 250mg Divalproex sodium and tentative approval for the ER tablets containing 500mg Divalproex sodium. These are used for treating various kinds of epileptic seizures, bipolar disorders and migraine. Divalproex ER is the generic name for the brand Depakote ER, marketed in the United States by Abbott Laboratories. According to IMS, the total market for Divalproex ER tablets in the US is \$910 million, of which the 250mg strength is \$114 million.

"Divalproex sodium Extended Release tablets is a novel drug delivery system based product, indigenously developed by Wockhardt's R&D team," said Wockhardt Chairman Habil Khorakiwala. "It is the strategic intent of Wockhardt to develop value-added generic products with novel / complex technologies. With nearly sixty products now in the market, Wockhardt's US business has seen a significant growth trajectory," he further added.

Wockhardt is one of the top 5 companies in the world to have received the highest number of 23 Abbreviated New Drug Approvals [ANDA] by the US FDA for 2008 [source Generics Bulletin 2009].

Wockhardt's Divalproex 250mg ER tablets will be launched in the US shortly. The 500mg Divalproex ER tablets will be launched in early August 2009, after the 180-days exclusivity period accorded to Mylan.

The API used in the tablets will be manufactured at Wockhardt US FDA approved facility at Ankleshwar, Gujarat and the Extended Release tablets will be manufactured at the US FDA certified formulation plant at Waluj, Maharashtra. Both the API and the product were developed in-house.

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 15 world-class manufacturing plants dotting various countries and continents that are compliant to international regulatory standards such as the US FDA, MHRA or 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 USA, UK, Ireland, France, and Germany with a multi-ethnic workforce from 14 different nationalities.