

Wockhardt Limited

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Wockhardt receives US FDA approval for generic version of Augmentin* Suspension

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Pharmaceutical and biotechnology major Wockhardt has received United States FDA approval for marketing an oral suspension of a combination of Amoxycillin and Clavulanate Potassium. Wockhardt's Chicago based subsidiary Morton Grove Pharmaceuticals received approval from the US FDA for marketing the suspension containing 250 mg/ 5ml of Amoxycillin and 62.5mg/ 5ml of Clavulanate potassium, which is used for treating several common infections, especially in children. The product is sold in the US by Glaxo SmithKline under the brand name Augmentin 250.

"Wockhardt is the first company to receive an ANDA approval for this strength of Augmentin" said Wockhardt Chairman Habil Khorakiwala. "Pediatric products are a major focus area for Morton Grove and this exclusive generic will be one of the several other unique pediatric products in our portfolio."

Wockhardt intends to launch this product in the US sometime in Q3 2009. According to IMS, the market for the 250/62.5 combination of Augmentin in the US is about \$32 million.

The product was developed as a part of a series of collaborative projects along with Cipla Limited, another pharmaceutical major from India. The product will be exclusively manufactured and supplied for Wockhardt by Cipla from its FDA approved facility in Goa, India.

In the prescription generic pharmaceutical market, Wockhardt has been consistently growing market shares for all its products. Wockhardt today markets over sixty products in the US.

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 dosage forms and marketing through the wholly-owned subsidiary in the US, enabling the company to capture maximum value. Morton Grove Pharmaceuticals is a leader in generic liquid products in the US and manufactures over 30 products in its facility near Chicago.

Wockhardt Limited 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 that are US FDA, MHRA or other global regulatory body approved, dotting various countries and continents. It has end-to-end integrated capabilities for its products, starting with manufacture of the oral and sterile API's, the dose 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.

^{*} Augmentin is the brand of Glaxo SmithKline