



Wockhardt receives tentative US FDA approval for generic version of Patanol® ophthalmic solution

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Pharmaceutical and biotechnology major Wockhardt has received tentative approval from the United States Food & Drug Administration (US FDA) for marketing 0.1% solution of Olopatadine hydrochloride eye drops, which is used for allergic conjunctivitis. Olopatadine is the generic name for the brand Patanol®, marketed in the United States by Alcon Laboratories Inc., now a subsidiary of Novartis AG. The patent covering this product is under litigation in the US courts and Wockhardt will launch the product after resolution of the same.

“This is a major ANDA approval for Wockhardt in the ophthalmic segment”, said Wockhardt Chairman Habil Khorakiwala. “Sterile products including ophthalmic products continue to form an increasing and important part of our US product portfolio. It is this diverse streams of technically complex products that is helping Wockhardt keep up its rapid pace of growth in the US”, he remarked.

Olopatadine is amongst the most widely used drugs in treating allergic conjunctivitis. Wockhardt is only one of three companies to receive a tentative approval for this product till date. According to IMS Health, the total market for this product in the US is about \$230 million.

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 manufactures the ophthalmic preparations in the US FDA certified sterile formulation plant at Waluj, Aurangabad. Like most of its other seventy plus ANDA approvals, this product was also 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.