
Wockhardt receives US FDA approval for Prostate drug Alfuzosin tablets

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Pharmaceutical and biotechnology major Wockhardt has received tentative approval from the United States Food & Drug Administration (US FDA) for marketing the 10mg extended release tablets of Alfuzosin Hydrochloride, which is used for treating Benign Prostatic Hyperplasia (BPH or non-cancerous enlargement of prostate). Alfuzosin is the generic name for the brand Uroxatral, marketed in the United States by Sanofi-Aventis. The patents covering this product are under litigation in the US courts and Wockhardt will launch the product after resolution of the same. According to IMS, the total market for Alfuzosin tablets in the US is about \$203 million. No generic version of this product has been launched so far in the United States.

“This is the second modified-release product approval for Wockhardt in the past five days and our fourth this year,” said Wockhardt Chairman Habil Khorakiwala. “It has been Wockhardt’s focus over the years, to develop products based on difficult technologies, and the efforts are now rapidly bearing fruit. This is another product where our backward integration approach will help us gain competitive advantage,” he stated.

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-file, gains advantages of being an early entrant.

The Alfuzosin tablets will be manufactured at the US FDA certified formulation plant at Waluj in Aurangabad and it will use API, which is also being manufactured by Wockhardt in its FDA approved plant. Both the API and the tablets were 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 technology-driven global pharmaceutical and biotechnology major with an innovative multi-disciplinary research and development programme. It has 5 research centres and 14 world-class manufacturing plants dotting various countries and continents that are compliant to international regulatory standards such as the US FDA, MHRA and 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 US, UK, Ireland and France with a multi-ethnic workforce from 14 different nationalities.