

Wockhardt gets FDA nod for generic treatment of enlarged prostate

15 August 2012 | News | By BioSpectrum Bureau

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Mumbai: Pharmaceutical and biotechnology major Wockhardt has received final approval from the US Food & Drug Administration (US FDA) for marketing 10mg extended release tablets of Alfuzosin hydrochloride, which is used in treatment of Benign Prostatic Hyperplasia (BPH) or enlarged prostate.

Alfuzosin is the generic name for the brand Uroxatral, marketed in the US by Sanofi-Aventis. Wockhardt is launching the product immediately.

Wockhardt will be manufacturing the Alfuzosin hydrochloride API in its facility at Ankleshwar, India, and the extended-release tablets of Alfuzosin at its facility in Aurangabad, India. The technology for the API and the capsules were developed in-house.

According to IMS Health, the total market for this product in the US is about \$81.5 million. A substantial portion of men above the age of 60 suffer from BPH. Wockhardt also markets other drugs in the same therapeutic group in the US.

"Developing extended release formulation has been a core competency of Wockhardt's R&D over the years," said Dr Habil Khorakiwala, Wockhardt founder chairman & group CEO. "Extended Release Alfuzosin is yet another product in the NDDS technology space," he further added.

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 few players to market technically challenging products, has reaped the advantage of being an early entrant.