

URGENT
PRESS RELEASE



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Wockhardt receives US FDA approval for the generic version of Toprol XL® , a cardiac drug

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Pharmaceutical and biotechnology major Wockhardt has received final approval from the United States Food & Drug Administration (US FDA) for marketing the 25mg, 50mg, 100mg and 200mg extended-release tablets of Metoprolol succinate which is used for 24-hour control of hypertension, treatment of angina and in improvement of survival after heart attack. Metoprolol succinate is the generic name for the brand Toprol XL®, marketed in the United States by Astra Zeneca. The product is being launched immediately.

“Metoprolol succinate extended release tablets is one of the most challenging oral pharmaceutical products to develop and stabilize, a fact demonstrated by the fact that Wockhardt will be only the second generic version of Toprol XL® in the market today” said Wockhardt Chairman Habil Khorakiwala. “Wockhardt’s ANDA program focuses on high-value, hi-tech products such as complex extended release products. We have also created very specialized and large manufacturing capacity to manufacture this product, which will ensure uninterrupted supply”.

Metoprolol succinate extended release is one of the most widely prescribed hypertension and angina drugs valued at over \$1.1 billion in the United States. Wockhardt will be only the second generic version of this technically demanding product in the US market, apart from the brand and its authorized generic.

In the US generic pharmaceutical market, Wockhardt has been consistently growing market shares for all its products. With products such as Metoprolol succinate ER tablets, Wockhardt’s US business will receive an enormous fillip.

The tablets will be manufactured at the US FDA certified formulation plant at, Aurangabad. 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.

Wockhardt Limited is a technology-driven pharmaceutical and biotechnology company with an active multi-disciplinary research programme employing over 500 scientists. Its new drug discovery programme has yielded several promising lead molecules, one of which is now in Phase II human clinical trials. The US and European Union contribute to around 69% of Wockhardt’s sales.

Toprol XL® is a registered trademark of Astra Zeneca.

For more information, visit www.wockhardt.com
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