

## **PRESS RELEASE**

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Mumbai, Thursday, October 24, 2013

# Unichem Laboratories receives ANDA approval from USFDA for AMLODIPINE BESYLATE TABLETS

Unichem laboratories Limited are pleased to announce that it has received ANDA approval from the United States Food and Drug Administration (U.S. FDA) for Amlodipine Besylate Tablets.

Amlodipine Besylate Tablets USP 2.5mg, 5mg and 10mg are therapeutically equivalent to NORVASC® Tablets 2.5mg, 5mg and 10mg from Pfizer Inc.

Amlodipine Besylate Tablet USP is a calcium channel blocker indicated for the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.

The product will be commercialized from Unichem's Goa plant. Active pharmaceutical ingredient i.e., Amlodipine Besylate used for this ANDA is also made in house at Roha plant.

Currently, there are 6-7 companies are dominating the US market. The current market size is around US\$ 45~50 Million.

### About Unichem Laboratories Limited

Unichem Laboratories Limited is an International, integrated, speciality pharmaceutical Company. It manufactures and markets a large basket of pharmaceutical formulations as branded generics as well as generics in India and several other markets across the world. In India, the Company is a leaded in niche areas of cardiology, neurology and other orthopadics and anti-infectives. The Company has strong skills in product development, process chemistry and manufacturing of complex API as well as dosage forms.





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More information about the Company can be found at www.unichemlabs.com

#### **Contacts:**

Mr. M Gundu Rao / Mr. K Subharaman

Ph: +91-22-66888 380 Ph: +91-22-66888 404

E-mail: gundurao@unichemlabs.com

subharamank@unichemlabs.com

Mr. Rakesh Parikh/ Mr. Monish Shah

Ph: +91-22-66888 414 Tel: +91-22-66888 509

E-mail: rparikh@unichemlabs.com

monish.shah@unichemlabs.com

Disclaimer: This press release includes forward-looking statements. We have based these forward-looking statements on our current expectations and projections about future events. Such statements involve known and unknown risks, uncertainties and other factors that may cause actual results to differ materially. Such factors include, but are not limited to, changes in local and global economic conditions, our ability to successfully implement our strategy, the market acceptance of and demand for our products, our growth and expansion, technological change and our exposure to market risks. By their nature, these expectations and projections are only estimates and could be materially different from actual results in the future.

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