



**UNICHEM  
LABORATORIES LTD.**

Fax No : 91 (22) 2678 4391 / 5198  
Tel. No. : 91 (22) 66888333  
Website : <http://www.unichemlabs.com>  
CIN : L99999MH1962PLC012451.

**Registered & Corporate Office :** Unichem Bhavan, Prabhat Estate, S. V. Road, Jogeshwari (West), Mumbai-400102, INDIA.

December 8, 2015

Ref: Stock-exchange/2015-16

Department of Corporate Services  
Bombay Stock Exchange Ltd.  
Phiroze Jeejeebhoy Towers,  
Dalal Street,  
Mumbai- 400 001

Mr. Hari K  
Asst. Vice President - Operations  
National Stock Exchange of India Ltd  
Exchange Plaza, Bandra – Kurla Complex  
Bandra (East), Mumbai – 400 051

Dear Sir,

**Ref: BSE Scrip Code -506690 : NSE Symbol – UNICHEMLAB**  
**Sub: Disclosures under Reg. 30 of SEBI (Listing Obligations & Disclosure Requirements) Regulations, 2015.**

Pursuant to Regulation 30 of SEBI (Listing Obligations & Disclosure Requirements) Regulations, 2015, please find enclosed herewith the press release pertaining to receipt of Final ANDA approval from United States Food and Drug Administration (U.S. FDA) for Irbesartan.

Please take this on record.

Thank you,

Yours Faithfully,  
For UNICHEM LABORATORIES LIMITED

**NEEMA THAKORE**  
*Head – Legal & Company Secretary*



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Mumbai - 400 102.  
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Fax. No: +91 (22) 267 843 91/ 5198  
CIN: L99999MH1962PLC012451

### **Press Release**

**Mumbai, Tuesday December 08, 2015**

#### **Unichem Laboratories receives Final ANDA approval from USFDA for Irbesartan Tablets USP**

Unichem Laboratories Limited is pleased to announce that it has received Final ANDA approval (Tentative Approval was received earlier) from the United States Food and Drug Administration (USFDA) for Irbesartan Tablets USP.

Irbesartan Tablets USP 75mg, 150mg and 300mg are therapeutically equivalent to Avapro Tablets, 75mg, 150mg and 300 mg of Sanofi-aventis U.S.LLC.

Irbesartan is indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents. Irbesartan is also indicated for the treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria (>300 mg/day) in patients with type 2 diabetes and hypertension. In this population, Irbesartan reduces the rate of progression of nephropathy as measured by the occurrence of doubling of serum creatinine or end-stage renal disease (need for dialysis or renal transplantation).

The product will be commercialized from Unichem's Ghaziabad plant. Active Pharmaceutical Ingredient will also be made in house at Pithampur API Plant.



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### **About Unichem Laboratories Limited**

Unichem Laboratories Limited is an international, integrated, specialty 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 leader in niche therapy areas of cardiology, neurology, orthopedics and anti-infectives. The company has strong skills in product development, process chemistry and manufacturing of complex API as well as dosage forms. More information about the company can be found at [www.unichemlabs.com](http://www.unichemlabs.com)

#### **For more information please contact:**

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**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.*