



**Press Release**

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Strides Arcolab Limited,  
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BSE: 532531  
NSE: STAR

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**STRIDES ARCOLAB ANNOUNCES USFDA APPROVAL FOR  
LABETALOL HYDROCHLORIDE INJECTION, USP – TOTAL  
APPROVALS IN STERILE SPACE AT 18**

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Strides Arcolab Limited (Strides) today announced receipt of ANDA approval for Labetalol Hydrochloride (HCl) injection, USP, 100 mg per 20 mL and 200 mg per 40 mL, Multi-dose Vials. This is expected to be launched shortly .

Ravi Seth, Chief Executive Officer – International Operations of Strides stated : “ We are pleased to announce this addition to the list of approved sterile injectable products for the US market which is another important milestone in our JV partnership with Sagent “

Labetalol is the third product launched under the partnership between Strides and Sagent Pharmaceuticals . Under this partnership , Strides and Sagent are jointly developing, supplying and marketing more than 25 injectable products for the U.S. market.

**About Labetalol Hydrochloride**

Labetalol HCl Injection is the generic equivalent of Prometheus Laboratories’ Trandate® (Labetalol HCl) Injection. Labetalol HCl Injection is an adrenergic receptor blocking agent that has both selective alpha1-adrenergic and non-selective beta-adrenergic receptor blocking actions that is used to control blood pressure in severe hypertension.

Labetalol HCl Injection is contraindicated in bronchial asthma, overt cardiac failure, greater than first degree heart block, cardiogenic shock, severe bradycardia, other conditions associated with severe and prolonged hypotension, and in patients with a history of hypersensitivity to any component of the product. Beta-blockers, even those with apparent cardioselectivity, should not be used in patients with a history of obstructive airway disease, including asthma.

### **About Strides Arcolab Limited:**

Strides Arcolab, listed on the Bombay Stock Exchange Limited (532531) and National Stock Exchange of India Limited (STAR), is a global pharmaceutical company headquartered in Bangalore, India that develops and manufactures a wide range of IP-led niche pharmaceutical products with an emphasis on sterile injectables.

The company has 14 manufacturing facilities across 6 countries, including its joint venture with Aspen in India and has a marketing presence in more than 60 countries in developed and emerging markets. Manufacturing is ably supported by a 350-scientist strong global R&D Centre located in Bangalore. Additional information is available at the company's website at [www.stridesarco.com](http://www.stridesarco.com).

### **About Sagent Pharmaceuticals, Inc.**

Sagent Pharmaceuticals, founded in 2006, is a privately held specialty pharmaceutical company focused on developing, manufacturing, sourcing and marketing pharmaceutical products, with a specific emphasis on injectable products. Sagent has created a unique, global network of resources, comprised of rapid development capabilities, sophisticated manufacturing and innovative drug-delivery technologies, quickly yielding an extensive portfolio of pharmaceutical products that fulfills the evolving needs of patients. Sagent currently has more than 200 products in development.

To Discover Injectables Excellence™ and learn more about Sagent, please visit [www.SagentPharma.com](http://www.SagentPharma.com).

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