

## PRESS RELEASE:

# Indoco receives ANDA approval for Glimepiride tablets from USFDA

**April 18, 2013, Mumbai:** Indoco Remedies Ltd., a fast growing pharma company with a global presence, has received the USFDA approval for its Abbreviated New Drug Application (ANDA) for **Glimepiride 1mg, 2mg & 4mg tablets**.

Glimepiride is indicated for type-2 diabetes mellitus treatment as an added therapy with diet and exercise to improve glycemic control in adults. The market size of this product in the US is US\$ 90 million and the API consumption is approx. 2000 kgs growing at 11.2%.

*“This is the first ANDA approval for solid dosages for Indoco and the Company is fully integrated to manufacture this product. The product will be launched in the US in the month of May 2013”,* said Ms. Aditi Kare Panandikar, Managing Director, Indoco Remedies Ltd.

Four of Indoco’s products are already available in the US market against the ANDAs filed and approved through partners. Additionally, Indoco has 37 ANDAs at various stages, out of which, 13 will be in the Company’s name and the rest through partners in the US market.

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### **About Indoco Remedies Limited:**

Indoco Remedies Limited, headquartered in Mumbai, is a fully integrated, research-oriented global pharmaceutical company with a strong presence in 80 countries including USA & UK. Indoco, a USD 140 million company, employs over 5500 people including 200 skilled scientists.

The company has 8 manufacturing facilities, 5 for Finished Dosages and 3 for APIs, supported by a state-of-the-art R&D centre at Rabale, Navi Mumbai. The facilities have been approved by various regulatory authorities such as UK-MHRA, USFDA, TGA-Australia, JAZMP- Slovenia, MCC-South Africa, Darmstadt – Germany, NDA-Uganda, TFDA-Tanzania, SBD-Yemen, MOH-Ukraine, PPB-Kenya and FDB-Ghana.

Indoco manufactures a wide range of pharmaceutical products for the Indian and international markets. It generates more than 50 million prescriptions annually from over 2,00,000 doctors in India. Indoco’s 8 domestic marketing divisions cater to different therapeutic segments including Respiratory, Anti-Infectives, Dental Care, Pain Management, Gastroenterology, Ophthalmics, Cardiovascular, Anti-Diabetics etc. Top Indoco brands include Febrex Plus, Cyclopam, Sensodent-K, ATM, Vepan, Cital, Oxipod, Sensoform, Cloben-G, Karvol Plus and Tuspel Plus. Some of the recently launched products like MCBM-69, Glychek, Methycal, Rosuchek-D and Omegachek have become sizeable brands. On the international front, the Company has tie-ups with large reputed generic companies like Watson- USA, ASPEN-South Africa and DSM-Austria.

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