

Indoco Remedies receives USFDA nod for its manufacturing facility (Goa Plant II)

Mumbai, May 25, 2016: Indoco Remedies Ltd. has received the Establishment Inspection Report (EIR) from US Food and Drug Administration (USFDA) for its Sterile and Solid Dosages facility (Goa Plant II) situated at L-32/33/34 Verna Industrial Estate, Goa. This approval confirms the closure of inspection conducted in July'2015.

The previous USFDA inspections of this facility were held in October 2005, February 2011 and August 2013. The Company has already received the approval (EIR) for its other solid dosage facility (Goa Plant I) in the month of March'2016.

“With approval by USFDA of manufacturing facilities in Goa, the Company’s commitment to quality systems stands validated. This will pave the way for speedy ANDA approvals and product launches in US”, said Aditi Kare Panandikar, Managing Director of Indoco Remedies Ltd.

Goa Plant II has a capacity to manufacture 30 million vials/bottles of ophthalmic solutions/suspensions and 400 million tablets.

Apart from approval from US FDA, the manufacturing facilities in Goa are also approved by EU- GMP, TGA-Australia, besides others.

About Indoco Remedies Limited:

Indoco Remedies Ltd., headquartered in Mumbai, is a fully integrated, research- oriented pharma Company with presence in 55 countries. Indoco, a USD 150 million Company, employs over 5500 people including 300 skilled scientists.

The Company has 8 manufacturing facilities, 5 of which are for FDFs and 3 for APIs, supported by a state-of-the-art R&D Centre and a CRO facility. The facilities have been approved by USFDA, UK-MHRA, TGA-Australia, MCC-South Africa, etc. Indoco develops and manufactures a wide range of pharmaceutical products for the Indian and international markets. It generates more than 60 million prescriptions annually from around 2,00,000 doctors in India. Indoco has 10 domestic marketing divisions with a strong brand portfolio in various therapeutic segments including Respiratory, Anti-Infective, Dental Care, Pain Management, Gastro-intestinal, Ophthalmic, Cardiovascular, Anti-Diabetics, Anti-Obesity, etc. Top Indoco brands include Cyclopam, Febrex Plus, Sensodent-K, ATM, Oxipod, Cital, Sensoform, Cloben-G, Sensodent-KF, Karvol Plus, Glychek, Vepan, Tuspel Plus, Flamar, etc. On the international front, Indoco has tie-ups with large generic companies like Watson (Actavis) – USA and ASPEN-South Africa.

For more details on Indoco, you may visit www.indoco.com

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