

# PRESS RELEASE

## **Indoco receives EIR for its manufacturing facilities in Goa (Plant II & III)**

**Mumbai, November 25, 2019:** Indoco Remedies Limited announced today, the receipt of Establishment Inspection Report (EIR), from the US Food and Drug Administration (USFDA) for its sterile facility (Plant II) and solid dosages facility (Plant III) at Verna, Goa for the inspection carried out between 7th October to 15th October, 2019. This was a Pre-Approval Inspection for a sterile injectable product, with 2 observations on Form 483s, which is now concluded as closed.

The inspection classification of this site has been determined as VAI (Voluntary Action Indicated) by the USFDA.

Commenting on the receipt of the EIR, **Ms. Aditi Kare Panandikar, Managing Director – Indoco Remedies Ltd.**, said, “We have received the EIR in just over a month’s time from the date of inspection. Excelling at Quality and Compliance is one of our top priorities, as we remain committed to meeting and exceeding standards set by the regulatory agencies globally.”

This second successful PAI (Pre-Approval Inspection) at the site in less than 6 months indicates steady progress in review of Indoco’s pending ANDAs. The Company has 39 ANDAs, pending for approval from this site”.

### **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 140 million Company, employs over 6000 people including more than 300 skilled scientists.

The Company has 9 manufacturing facilities, 6 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, PMDA-Japan, etc. Indoco develops and manufactures a wide range of pharmaceutical products for the Indian and international markets. It generates more than 70 million prescriptions annually from around 3,10,000 doctors belonging to various specialties. Indoco has 9 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, Oxipod, Cital, ATM, Cloben-G, Sensoform, Sensodent-KF, Karvol Plus, Glychek, Kidodent, Carmicide, Bactogard, 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](http://www.indoco.com)

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