



# PRESS RELEASE

## USFDA concludes inspection of Indoco's Sterile facility (Plant II)

**June 5, 2019, Mumbai:** The US Food and Drug Administration (USFDA) conducted audit at Indoco's sterile manufacturing facility in Verna, Goa (Plant II) from 27<sup>th</sup> May'19 to 4<sup>th</sup> June'19, issuing 4 observations (483s). These observations are procedural in nature, not pertaining to data integrity. The Company will submit its responses shortly.

Commenting on this development, **Ms. Aditi Kare Panandikar, Managing Director – Indoco Remedies Ltd.** stated, "The recent USFDA inspection was a scheduled PAI, i.e., Prior Approval Inspection for Injectable products, filed from this facility. We are hopeful for an early and successful closure of this audit, which will expedite approvals of the pending ANDAs."

### 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 5500 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, MCC-South Africa, 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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