

# PRESS RELEASE

## **Indoco's CRO – ANACIPHER clears USFDA inspection with ZERO 483**

Mumbai, August 12, 2019 : Indoco Remedies Ltd. announced today that its Clinical Research Organisation, Anacipher, located at Hyderabad had undergone a walk-in surveillance inspection by the United States Food and Drug Administration (division of New Drug Bioequivalence Evaluation) from 5<sup>th</sup> August to 9<sup>th</sup> August, 2019. The inspection successfully concluded without any observations and no form 483 is issued.

“This is the fourth successive USFDA inspection with ZERO 483 for our CRO – AnaCIPHER. We are committed to strict adherence to regulatory guidance and maintaining highest standards in delivering quality services to our clients.”, stated Ms. Aditi Kare Panandikar, Managing Director, Indoco Remedies Limited.

The CRO - AnaCIPHER conducts Bio-Equivalence and Bio-Availability (BA/BE) studies at its facility spread over an area of 30,000 sq. ft. with 98 beds. CRO also has expertise in Bio-Analytical work for new chemical entities (Phase I-III studies).

### **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, 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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