



PRESS RELEASE

Indoco's AnaCipher CRO clears USFDA inspection with Zero 483s

Mumbai, September 19, 2022: Indoco Remedies Ltd. announced today that its Clinical Research Organisation, AnaCipher, located in Hyderabad, was inspected by the United States Food and Drug Administration from September 12 to September 16, 2022. The clinical phase of inspection covered three BA/BE studies submitted by clients to the USFDA and was successfully concluded with zero 483s.

“This is the seventh successive USFDA inspection with ZERO 483s for AnaCipher CRO. We are committed to strict adherence to all applicable guidelines and regulations and maintaining the highest quality standards in delivering quality services to our clients.”, **said Ms. Aditi Kare Panandikar, Managing Director, Indoco Remedies Limited.**

About AnaCipher CRO:

AnaCipher CRO, based in Hyderabad, is a USFDA inspected clinical research facility and is spread over 40,000 sq. ft area with 98 beds and staffed by experienced professionals providing clinical trial solutions and conducts Bioequivalence and Bioavailability (BA/BE) studies at its facility. The CRO also has expertise in Bioanalytical work for new chemical entities (Phase I-III studies) for pharmaceutical companies globally. The CRO has successfully completed more than 500 studies in multiple therapeutic areas such as, cardiovascular, diabetes, oncology, anti-retrovirals and antacids.

About Indoco Remedies Limited:

Headquartered in Mumbai, Indoco is a fully integrated, research-oriented pharmaceutical company with a presence in 55 countries. The Company's turnover is US\$ 198 million with a human capital of 6000 employees, including over 300 skilled scientists and Field Staff who are the strength of the organization.

The Company has 9 manufacturing facilities, 6 for Finished dosages and 3 for APIs, supported by a state-of-the-art R&D facility in Navi Mumbai and a Clinical Research Organization in Hyderabad. The facilities have been approved by most global Regulatory Authorities, including USFDA and UK-MHRA.

Indoco develops and manufactures a wide range of pharmaceutical products for the Indian and international markets. It generates more than 83 million prescriptions annually from over 3,00,000 doctors belonging to various specialties.

The Company's R&D team develops non-infringing processes for APIs, formulations and various dosage forms like Immediate Release Tablets, Capsules, Multi-Unit Pellet Systems (MUPS), Pulsatile Drug Delivery Systems, Sterile Ophthalmic Ointments, Ophthalmic Gels, Suspensions and Solutions, Extended Release Tablets with matrix technology, complex ophthalmic products like emulsions and nano suspensions, as well as a range of injectable solutions, suspensions and depot based long-acting injectables.

Indoco has 8 domestic marketing divisions with a strong brand portfolio in various therapeutic segments including Stomatologicals, Gastro-Intestinal, Respiratory, Anti-Infectives, Vitamins/Minerals/Nutrients, Cold & Cough, Ophthalmics, Antifungal, Antidiabetic & Cardiovascular, Urology, and several others. Top Indoco brands include Cyclopam, Febrex Plus, Sensodent-K, Karvol Plus, ATM, Oxipod, Cital, Cital UTI, Sensoform, Sensodent-KF, Cloben-G, Tuspel Plus, Dropizin, Tuspel LS, Glychek, Kidodent, Carmicide, Rexidin, MCBM 69, Methycal, Cal-Aid, Macuchek, Mofloren, Irivisc, PGVISC, Nepachek, Noxa, Subitral, Aloja, Glychek, etc.

Indoco exports a variety of products to regulated and emerging markets, including the USA and EU. The Company has tie-ups with large generic companies and works in close coordination with its customers to leverage core competencies.

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

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