

Indoco Remedies CRO AnaCipher Gets One Form 483 From USFDA

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Mumbai: Indoco Remedies Limited announced that its Clinical Research Organisation, AnaCipher, located at Hyderabad has received one Form 483 from the U.S. Food and Drugs Administration (USFDA) at the end of the inspection.

The on-site inspection was conducted from 3rd March, 2025 to 7th March, 2025, by investigators from Bioresearch Monitoring Program (BIMO) and Office of Study Integrity & Surveillance (OSIS) of US FDA.

The inspection covered both clinical and bioanalytical phases of three Bioavailability and Bioequivalence (BA/BE) studies submitted by clients, to the US Food and Drug Administration (FDA).

“This is an exciting step in our journey of excellence and a validation of our adherence to applicable regulations and maintaining the highest standards in delivering quality services to our clients.” stated Ms. Aditi Kare Panandikar, Managing Director, Indoco Remedies Limited.

Indoco is a fully integrated, research-oriented pharmaceutical company with a strong global presence. The Company’s turnover is US\$ 212 million with a human capital of over 6000 employees, including over 400 skilled scientists and field staff. The Company has 11 manufacturing facilities, 7 for FDFs and 4 for APIs, supported by a state-of-the-art R&D Centre and a CRO facility. The facilities have been approved by most of the 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 106 million prescriptions annually from over 2,35,000 doctors belonging to various specialties. Indoco has 8 domestic marketing divisions a strong brand portfolio in various therapeutic segments including Gastro-intestinal, Respiratory, Anti-Infective, Stomatologicals, Ophthalmic, Nutritionals, Cardiovascular, Anti-Diabetics, Pain Management, Gynaecology etc. Top Indoco brands include Cyclopam, Febrex Plus, Sensodent-K, Karvol Plus, ATM, Oxipod, Cital, Sensoform, Sensodent-KF, Aloja, Glychek, Kidodent, Subital, Rexidin, MCBM 69, Methycal, Dropizine, Noxa, Homide, Cal-Aid, etc. On the international front, Indoco has tie-ups with large generic companies across the globe.