

Indoco Remedies shares drop 6% after US FDA issues Form 483 For Hyderabad CRO unit

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Indoco Remedies Ltd. has announced that its Clinical Research Organisation, AnaCipher, located at Hyderabad, has completed its 5-day comprehensive USFDA inspection. The on-site inspection was conducted from March 3-7, 2025, by investigators from Bioresearch Monitoring Program (BIMO) and Office of Study Integrity & Surveillance (OSIS) of USFDA.

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). The facility received one Form 483 at the end of the inspection, which will be responded within timeframe.

Commenting on the development, Aditi Kare Panandikar, Managing Director, Indoco Remedies Ltd. said, “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.”

Indoco is a fully integrated, research-oriented pharmaceutical company with a strong global presence and has reported a turnover of US\$ 212 million. 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, Rexitin, MCBM 69, Methycal, Dropizine, Noxa, Homide, Cal-Aid, etc.

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