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

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Indoco Remedies' stock fell 6% after its clinical research division, AnaCipher, received a Form 483 from the United States Food and Drug Administration (USFDA). As of 9:18 AM, the shares were trading 4.64% lower at Rs 220.05.

The inspection, conducted from March 3 to March 7, 2025, took place at the Hyderabad-based facility under the USFDA's Bioresearch Monitoring Program (BIMO) and the Office of Study Integrity & Surveillance (OSIS).

The inspection covered both clinical and bioanalytical phases of three Bioavailability and Bioequivalence (BA/BE) studies submitted by clients to the FDA. At the end of the process, the facility received one Form 483, a notice highlighting objectionable conditions. Indoco Remedies has stated that it will respond to the FDA's observations within the stipulated timeframe.

Despite the regulatory hurdle, Indoco Remedies' Managing Director, Aditi Kare Panandikar, remains optimistic. She emphasized that the inspection validates the company's adherence to global regulatory standards and commitment to quality.