

Hot Pursuit News

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Indoco Remedies slides after Hyderabad facility gets one form 483 from USFDA

Indoco Remedies declined 3.22% to Rs 224.20 after its Clinical Research Organization, AnaCipher, located in Hyderabad, received one Form 483 from the United States Food and Drug Administration (US FDA) at the end of an inspection.

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

The facility received one Form 483 at the end of the inspection, to which a response will be provided within the required timeframe.

Aditi Kare Panandikar, MD, Indoco Remedies, "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 Remedies is engaged in the manufacturing and marketing of formulations (finished dosage forms) and active pharmaceutical ingredients (APIs).

The pharmaceutical company reported a standalone net loss of Rs 10.23 crore in Q3 FY25 as against a net profit of Rs 20.01 crore posted in Q3 FY24. Revenue from operations stood at Rs 364.91 crore in the third quarter of FY25, down 18.61% as against Rs 448.38 crore posted in Q3 FY24.