

Indoco Remedies' AnaCipher says USFDA has completed inspection of Hyderabad facility

Shares of Indoco Remedies Ltd ended at ₹232.60, down by ₹1.85, or 0.79%, on the BSE.

By Jomy Jos Pullokaran

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Drug firm Indoco Remedies Ltd on Monday (March 10) announced that its clinical research win AnaCipher, based in Hyderabad, has been inspected by the United States Food and Drug Administration (USFDA).

The inspection, conducted from March 3 to March 7, 2025, was carried out by investigators from 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 US Food and Drug Administration (FDA). The facility received one Form 483 - a notice of objectionable conditions - at the end of the inspection, which the company says it will respond to before the deadline.

"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," said Aditi Kare Panandikar, Managing Director, Indoco Remedies.

Last year, Indoco Remedies said the company's facility in Verna, Goa, had received a warning letter from the USFDA. The facility's Plant II and Plant III, which are located at L 32, 33-34 at the Verna Industrial Estate, received an Official Action Indicated (OAI) classification from the US drug regulator on October 11.

"The company remains closely committed to working closely with the USFDA and continues to enhance its compliance on an ongoing basis. We will work with the USFDA to resolve these issues at the earliest," Indoco Remedies said in a statement.

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