

USFDA Concludes Inspection of Indoco Remedies' AnaCipher Unit in Hyderabad

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Indoco Remedies' AnaCipher unit in Hyderabad was inspected by USFDA, receiving one Form 483, while its Goa facility remains under regulatory scrutiny.



Indoco Remedies announced that its Hyderabad-based clinical research unit, AnaCipher, underwent an inspection by the United States Food and Drug Administration (USFDA).

The inspection, conducted between March 3 and March 7, 2025, was carried out under the USFDA's Bioresearch Monitoring Program (BIMO) and the Office of Study Integrity & Surveillance (OSIS).

Scope of the USFDA Inspection

The inspection covered both clinical and bioanalytical phases of three Bioavailability and Bioequivalence (BA/BE) studies submitted by clients to the USFDA.

At the end of the inspection, the facility received one Form 483, a notice issued by the US regulator indicating objectionable conditions. Indoco Remedies stated that it will respond to the Form 483 within the prescribed deadline.

Commenting on the inspection, Aditi Kare Panandikar, Managing Director of Indoco Remedies, 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."

Past Compliance Challenges in Goa Facility

This USFDA inspection follows compliance challenges faced by Indoco Remedies last year at its manufacturing facility in Verna, Goa. On October 11, 2024, the USFDA issued a warning letter to the company, classifying its Plant II and Plant III, located at L 32, 33-34 in Verna Industrial Estate, under the Official Action Indicated (OAI) category.

In response, Indoco Remedies reaffirmed its commitment to regulatory compliance and its ongoing engagement with the USFDA. "The company remains closely committed to working 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," the company said in a statement.

Stock Performance

On March 11, 2025, Indoco Remedies share price traded 4.86% lower at ₹220.40 at 9:28 AM (IST). Indoco Remedies' share price reached a 52-week high of ₹385.50, and a 52-week low of ₹190. As per BSE, the total traded volume for the stock stood at 1,228 shares with a turnover of ₹2.72 lakhs.

At the current price, Indoco Remedies shares are trading at a price-to-earnings (P/E) ratio of 36.92x, based on its trailing 12-month earnings per share (EPS) of ₹5.79, and a price-to-book (P/B) ratio of 1.78, according to exchange data.

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Investments in the securities market are subject to market risks, read all the related documents carefully before investing.

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