# USFDA Inspects Indoco's AnaCipher Unit, Issues Form 483

11 Mar 2025 , 01:48 PM

Hyderabad based AnaCipher, clinical research division of Indoco Remedies Ltd, US FDA (United States Food & Drug Administration) inspected the plant. Investigators at USFDA's Bioresearch Monitoring Program (BIMO) & Office of Study Integrity & Surveillance (OSIS) conducted the inspection from March 3 to March 7 of 2025.

The audit was concentrated on the clinical as well as bioanalytical aspects of three Bioavailability as well as Bioequivalence (BA/BE) research study performed for customers as well as submitted to the USFDA. At the conclusion of the inspection, AnaCipher was issued one Form 483, which describes objectionable conditions observed by regulators. Indoco Remedies stated that it will respond to the Form 483 observations within the prescribed timeline.

Indoco Remedies Managing Director Aditi Kare Panandikar said the inspection reaffirms the company's commitment towards regulatory compliance and a high level of quality as a manufacturer. The inspection marks an important milestone on AnaCipher's path to ensuring excellence in clinical research.

Indoco Remedies' manufacturing facility in Verna, Goa had received a warning letter from USFDA in October 2024. Plant II and Plant III, situated at L 32, 33-34 in the Verna Industrial Estate, were classified as Official Action Indicated (OAI) in the warning. Indoco Remedies reiterated its aim to collaborate with USFDA to enhance compliance measures and address regulatory issues." The company has promised to take appropriate corrective steps to address the identified issues and improve its compliance with regulations.