

FDA: Natco failed to follow quality control measures

Hyderabad, Jan 25: The US Food and Drug Administration (FDA) has noted that city-based Natco Pharma did not follow quality control measures “fully” at its formulation plant in Telangana.

The US drug regulator has made six observations after the completion of inspection of its Kothur formulation facility in Telangana, Natco said on Wednesday in a statement. “The responsibilities and procedures applicable to the quality control unit are not fully followed... The written stability testing programme is not followed,” FDA said in its inspection report.

The FDA had inspected the Kothur formulation facility between January 16-24, 2017, Natco Pharma said in a statement.

The company, however, stated that all observations are “correctable and procedural and it believes are minor in nature”. “The observations are related to complaint and incident investigations, stability backlog and procedural SOPs,” it said. Natco Pharma said it will provide due justifications and corrective action plan within next 15 working days to address the USFDA observations. “Laboratory control does not include the establishment of scientifically,” FDA report said. *PTI*