

FDA comments on quality system at Natco unit

SPECIAL CORRESPONDENT

HYDERABAD: Natco Pharma's formulation facility at Kothur, near Hyderabad, has received six observations, including one on the quality system after a recent inspection by the U.S. Food and Drug Administration (USFDA).

In its observations, the regulator said "the responsibilities and procedures applicable to the quality control unit are not fully followed. The written stability testing programme is not followed."

'Correctable, procedural'

Natco Pharma said the six observations, received after the inspection - conducted between January 16 and 24 - were, however, "correctable and procedural". The company believes that the observations are minor in nature, Natco Pharma said in a release. "The observations are related to complaint and incident investigations, stability backlog and procedural SOPs.

"The company will provide due justifications and corrective action plan within the next 15 working days," the drugmaker said.

The Kothur unit had also received a Establishment Inspection Report (EIR) from the U.S. FDA last August.