

# USFDA raises issues over Natco Pharma's formulations plant

## OUR BUREAU

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The US Food and Drug Administration (USFDA) has raised some issues after inspection of its Kothur formulations facility.

The inspection was conducted in the Kothur plant near here during January 16-24, 2017.

“At the end of the inspection, the facility received six observations, all of which are correctable and procedural and which the company believes are minor in nature,” Hyderabad-based Natco said in a release issued here on Wednesday.

The observations are related to complaint and incid-

ent investigations, stability backlog and procedural aspects.

Some of the observations include non-establishment/non-adherence to procedures designed to prevent microbiological contamination of drug products purporting to be sterile and ‘not well controlled’ disposition status of approved and quarantined drug product, and so on.

“The company will provide due justifications and corrective action plan with the next 15 working days to address the US FDA observations,” Natco said.

Natco's scrip gained 1.28 per cent on the BSE on Wednesday to close at ₹646.75.