

USFDA found ceiling leaks, stains at Sun Pharma plant

Rupali Mukherjee
@timesgroup.com

Mumbai: The US Food and Drug Administration (FDA) warning letter issued to Sun Pharma highlights serious concerns of sterility assurance in medicines, possibility of microbial contamination and ceiling leaks, as part of the manufacturing lapses at its Halol facility. While the FDA has asked for progress reports on certain issues, it has stated that it would evaluate the remediation actions in its follow-up inspection soon. Sun Pharma ended flat at Rs 792 on the BSE on Thursday.

The FDA investigator documented the presence of leaks in the form of water stains, ceiling damage and buckets with water collected from ceiling leaks in the manufacturing area, which could compromise the quality of the medicines manufactured at the facility. While the letter was issued last week, it is only now that the violations have been spelt out in detail by the regulator.

Though it seems that "da-

ta integrity" issues have not been flagged by the US regulator, the letter enlists "significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals". Also, the "methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with, CGMP", it adds.

The warning letter of December 17 is based on inspections carried out at Halol, a

DETAILS OUT

key plant for the company, from September 8-19, 2014. Since the company did not take "sufficient corrective action" after the Form 483 — observations on manufacturing standards — was issued, the warning letter followed after 15 months of the inspection, experts say.

Analysts say the letter materially allays investor concerns about further escalation, or long delays in remediation.

FDA has highlighted six concerns related to sterility assurance, possibility of microbial contamination, inadequacies in airflow systems and failure to establish and document accuracy and sensitivity of test methods. It has directed Sun Pharma to systematically improve the oversight of manufacturing quality to ensure sustainable quality assurance, and include a risk assessment regarding the practice of rejecting media fill vials without a written justification.

The company has to revert with steps taken as corrective action, within 15 working days of receipt of the letter.

During the inspection, the FDA noted that the company's engineering department investigated the leaks, but failed to address environmental control in the parenteral manufacturing area, or to determine how leaks in this area could compromise the quality of the aseptically-filled products. In response, the company has to provide a summary of the environmental data and other facility maintenance since the inspection.

Regulatory