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US Cites Torn Records, Unclean Toilets for Banning Sun's Plant

Analysts say import alert by the USFDA on the Gujarat facility was unlikely to cause any significant financial impact

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NEW DELHI

Torn documents, partially destroyed raw data showing undesirable results and unclean toilets were among the reasons cited by the US drug regulator for the ban it imposed last month on a Gujarat-based facility of Sun Pharma, the largest Indian drugmaker by market capitalisation.

"Drug products failing to meet established specifications and quality control criteria are not rejected," said a form 483 issued to the company, which spelt out violations as observed by US investigators at the Karkhadi facility during their audit in November 2013.

This plant, which manufactures the antibiotic Cephalosporin, accounts for less than 1% of the company's sales.

Analysts had pointed out that the import alert by the US Food and Drug Administration (FDA) on the facility was unlikely to cause any significant financial impact but said they awaited clarifications on the nature of violations.

"We identified multiple torn/partially destroyed raw data cGMP (current good manufacturing practices) manufacturing and quality records. Our review of these records identified the practice of maintaining duplicate versions of cGMP raw data records. Undesirable data was found to be changed in the official versions in order to meet specifications," said the FDA inspection report that ET has reviewed.

Violations Led to Ban on Sun's Karkhadi Facility

Last month, US drug regulator imposed ban on a Gujarat-based facility of Sun Pharma

The Karkhadi plant, which manufactures the antibiotic Cephalosporin, accounts for less than 1% of the Sun Pharma's sales

The ban on its plant last month was the first ever faced by Sun in any of its India-based facilities and triggered a 5% intra-day dip in share price

Sun Pharma said it has put remedial measures in place

VIOLATIONS OBSERVED BY US INVESTIGATORS

Multiple torn/ partially destroyed raw data cGMP manufacturing and quality records

Toilet for manufacturing operators at the plant was in "total disrepair" and lists concerns about poor housekeeping

Garbage dump spotted in the perimeter of the manufacturing area, apart from various forms of infestation

"We have sent our response to the FDA and given that the facility now has an import alert, it's clear that the FDA does not agree with our view. In this process, we have learnt and have resolved to work on further strengthening our systems and controls," a spokesperson told ET.

With regard to the torn documents and partially destroyed data, the company said it has put remedial measures in place. "The applicable SOP (standard operating procedure) in this case was not adhered to for which appropriate corrective action has been taken," Sun said in an email.

"The reason this was not detected as part of our internal compliance checks is due to the equipment not being CFR (code of federal regulation) compliant. We are now replacing this with CFR compliant equipment. In addition, we are ensuring that equipment at all locations is CFR compliant. Also appropriate disciplinary action has been taken."

The report, which makes 11 observations on deviations from US-prescribed quality standards, said the toilet for manufacturing operators at the plant was in "total disrepair" and lists concerns about poor housekeeping.

"The two urinals present in the washing and toilet facility provided for quality control laboratory male employees were found to drain directly onto the floor. Urine was found to be collected in and around an open drain. A strong smell of urine was observed throughout your firm's quality control environment," said the report signed off by FDA investigators Peter Baker and Dipesh Shah.

The poor washing and toilet facilities have been fixed, Sun said.

They also spotted a garbage dump in the perimeter of the manufacturing area, apart from various forms of infestation. "Buildings used in the manufacture, processing, packing or holding of drug products are not free of infestation by rodents, birds, insects and other vermin," the report said.

Sun has also addressed these issue, it said: "The observations are related primarily to the surroundings and supporting areas of the referred buildings. However, we have taken further corrective measures in this regard."

"While the poor maintenance issues can be sorted out, the gravity of charges on data destruction and tinkering with records cannot be undermined and is usually taken seriously by US FDA," said a former senior quality control executive at a rival firm, who reviewed the observations. He spoke on condition of anonymity.

He, however, didn't want to hazard a guess as to whether it could prompt more surprise inspections by the FDA at other sites of Sun, which has maintained a clean record till now. The bar on its plant last month was the first ever faced by the company in any of its India-based facilities and triggered a 5% intra-day dip in share price.

Prashant Nair of Citi Research dubbed the stock reaction "overdone". He said in a note: "This is a very small cephalosporins facility, with limited sales into the US. Besides its overseas manufacturing assets... Sun's plant at Halol (Gujarat) is the major feeder for its US business."

Sun had earlier faced an import alert on a US-based facility belonging to subsidiary Caraco and a warning letter over unit Taro's Canadian plant but both were successfully resolved. Facilities of many top India-based drug firms, including Ranbaxy Labs and Wockhardt, were blacklisted by the US regulator last year.

Regulatory.