

**SURPRISE CHECK**

# FDA inspection finds incomplete records at Sun Pharma plant

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MUMBAI

**I**nspectors of the US Food and Drug Administration (FDA) have seized some incomplete records during a surprise check this week at Sun Pharmaceutical Industries Ltd's formulation factory at Halol in Gujarat, people familiar with the development said.

"The inspectors have got some material evidence, which include records that are not properly maintained, among others that may or may not lead to negative observations by the US regulator," said one of the people who spoke on condition of anonymity.

Incomplete records and lack of data integrity are serious violations that lead to negative observations when regulators inspect drug factories.

Sun Pharma declined to comment.

The company, however, had clarified to the stock exchanges on Friday that its manufacturing facilities undergo many routine regulatory inspections from several countries where it exports products as part of the normal course of business.

"Conduct of each of these inspections per se has no material impact," it said. "Sun Pharma and its subsidiary have more than 15 manufacturing facilities spread across India. It markets products in more than 50 countries."

Sun Pharma's formulation factory at Halol is being inspect-

ed since Monday. This factory contributes about 15% to the company's US sales and 25% to its profit from US sales. Sun Pharma earns about 60% of its annual revenue from the US.

In May, the FDA had banned imports from another Sun Pharma factory in Karkhadi in Gujarat, which mostly manufactures active ingredients, following its earlier observations regarding the plant's compliance with the quality standards laid out by the regulator. FDA had alleged certain data integrity issues at the Karkhadi plant.

"A US import ban on the Halol unit, similar to that of its Karkhadi factory, will be a serious setback to Sun Pharma as this formulation plant contributes over 15% of its revenue from that market at present," said a sector analyst with a foreign brokerage who didn't want to be identified.

The Halol factory, which is comparatively older, could also be non-compliant with many of the latest good manufacturing practices laid out by the FDA in terms of technology and infrastructure, apart from the documentation issues, the analyst added.

The US regulator may be expanding its scrutiny to the company's other factories, including the two export-oriented ingredient production sites and two formulation units located in Gujarat, Maharashtra and Dadra and Nagar Haveli, *Mint* had reported on 23 May, quoting people familiar with the development.

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