

US FDA descends on Sun Pharma's Halol unit

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Drug maker Sun Pharma's manufacturing facility in Halol (Gujarat) is undergoing a surprise inspection by the US Food and Drug Administration (US FDA), it is learnt. The move may have been triggered by a number of recent recalls from the plant, sources, familiar with the development, said.

When contacted on phone, Sun Pharma spokesperson declined to comment.

In May, Sun Pharma's another manufacturing facility in Karkhadi, also in Gujarat, had received a warning letter from the US FDA after investigators identified violations of current good manufacturing practice and regulations for finished pharmaceuticals.

The American regulator, in its warning letter to Sun Pharma's Karkhadi plant, had also asked the company to expand its "internal review to any other facilities determined to be involved in, or affected by, inaccurate data reporting".

Sources said the latest inspection could have been triggered because despite the warning letter at Karkhadi plant, recalls by the company continued from Halol plant, which supplies significant amount of medicines to the US.

Of late, Sun Pharma recalled three important medicines from the US market. It recalled 40,000 bottles of Venlafaxine Hydrochloride extended-release tablets after it failed dissolution test. The company also recalled Gemcitabine for manufacturing issue (lack of sterility assurance) and Metformin for packaging problems (Gabapentin tabs found in Metformin bottles).

While all recalls were limited to specific batches, all three products are manufactured at Halol.

Following such developments, analysts were expecting an inspection in the plant soon. Recently, in a report brokerage Credit Suisse said, "We



REGULATORY WHIP

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- Sun Pharma had recalled 40,000 bottles of Venlafaxine Hydrochloride extended-release tablets, Gemcitabine and Metformin from the US market
- Halol plant was last inspected in September 2012
- According to sources, the plant contributes to around 40% of US sales and around 25% of consolidated profit of the company

expect higher FDA scrutiny during its next inspection at Sun Pharma's Halol facility given the recall of three products in last six months and import alert at Karkhadi plant," it says in a note.

Halol plant, one of the major facilities of Sun Pharma supplying to the US market, was last inspected in September 2012. According to industry sources, it contributes to around 40 per cent of US sales and around 25 per cent of consolidated profit of the company.

Results of the ongoing inspection at Sun Pharma's Halol plant would be significant given its importance to the company's US revenues as well as for its overall performance going forward.

Sun Pharma has recently

also agreed to buy Ranbaxy Laboratories, another domestic pharmaceutical major ailing from regulatory issues in the US. Ranbaxy's all four plants in India are currently facing ban in the American market.

On Wednesday, shares of Sun Pharmaceutical Industries ended at ₹859.65 on the Bombay Stock Exchange, down 0.06 per cent from their previous close.

Company