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Litmus test for Ranbaxy unit as FDA begins inspection

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New Delhi, 10 January

The US drug regulator's team is inspecting Ranbaxy's active pharmaceutical ingredient or API manufacturing factory at Toansa in Punjab, it is learnt.

The outcome of the inspection could be crucial for the company because 70-75 per cent of the APIs used in its formulations are understood to be manufactured at the factory, sources said.

A detailed email sent to Ranbaxy did not elicit any response.

The Toansa facility had come under the US drug regulator's scanner in late 2012. In December that year, the US Food and Drug Administration (US FDA) had issued a Form 483 to the company highlighting several violations in manufacturing practices at the API unit. According to sources, though the facility was not barred from supplying raw materials for manufacturing products meant to be sold in the US, the issues at the factory raised serious concerns in the management.

"API sourcing is very crucial while seeking product approvals in the US. If Ranbaxy manages a clean chit from FDA authorities, it may enable the company to confidently use inhouse APIs instead of outsourcing it," one of the sources said. Apart from manufacturing APIs at Toansa factory, Ranbaxy also outsources API from other manufacturers.

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Some officials, in the know of developments, also believe that problems at Ranbaxy's Mohali facility are also linked with failures at its Toansa unit. In September 2013, the US FDA imposed an import alert on Mohali solid dosage manufacturing facility, barring it from supplying any products to the US. The Mohali factory, located around 150 km from Toansa, is currently undergoing a consent decree with the US FDA to take corrective measures.

The inspection at the Toansa factory also assumes significance because if the company fails to satisfy the US regulatory authorities, it may add to the existing troubles for the company.

Currently, Ranbaxy's all key Indian formulation manufacturing facilities, in Paonta Sahib, Dewas, Batamandi and Mohali, are under US import alert and are barred from supplying any products to the US. While this has brought down the company's sales and profitability in the past few years, the remediation measures have also put a cost pressure on Ranbaxy, which also had to pay a hefty fine of $500 million to US authorities last year after pleading guilty of fraudulent activities.

Ranbaxy is awaiting approvals for various key products in the US, including generic versions of Novartis AG's hypertension drug Diovan. On Friday, Ranbaxy shares ended at ₹463.45 on the BSE, down 2.25 per cent from its previous close.

Regulatory