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US FDA warns Sun Pharma on plant lapses

TIMES NEWS NETWORK

Mumbai: India's largest drug maker Sun Pharma has received a warning letter from the US FDA for manufacturing lapses at its facility in Halol. The site is among the largest for Sun Pharma, and important for the company as it is used for producing multiple formulations, including injectables, which are mainly exported to the United States, its largest market.

The Halol facility was inspected by the US FDA in September 2014, following which the regulatory agency had notified around 23 issues that were seen to be in violation of standard manufacturing norms.

Regulatory trouble at Halol has already had an adverse impact on the firm. The Halol site has been a primary contributor to Sun's revenues from the US. Prior to the US FDA's objections raised last year, the Halol facility had accounted for about 10% or \$440 million of Sun Pharma's global revenues of \$4.3 billion. It has declined to around \$240 million post the FDA audits.

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