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USFDA finds procedural lapses at Wockhardt's U.S. facility

HYDERABAD: The U.S. Food and Drug Administration has found as many as 12 procedural lapses in Wockhardt's U.S. facility in Illinois.

The inspection, which was carried out by the FDA officials between January 22 and March 26, pointed out that the responsibilities and procedures applicable to the quality control unit were not in writing and fully followed.

"There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or the batch has already been distributed," the report said in one of the observations.

The quality control unit lacked authority to review production records to assure no errors occurred and fully investigate errors that had occurred, it further said.

The FDA has already issued warning letters to two of the Wockhardt's plants in India. In November last, the FDA issued an import alert, effectively a ban, against Wockhardt's Chikalthana plant in western India.

The FDA had imposed a ban on the company's Waluj plant in May. Wockhardt's Managing Director Murtaza Khorakiwala recently told analysts that the FDA had in March inspected the company's Chicago-based Morton Grove Pharmaceuticals unit, which accounts for more than 50 per cent of its sales in the United States.

When contacted, a company spokesperson declined to comment. — PTI

Regulatory