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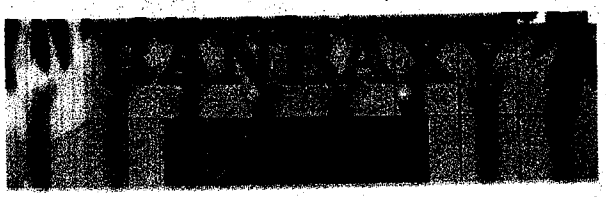
# Flies in Ranbaxy's Toansa plant's sample storage room, says FDA

PTI ■ HYDERABAD



Presence of flies in sample storage room, un-calibrated instruments in laboratory and non-adherence to sample analysis procedure were among the lapses found in Ranbaxy's Toansa plant that led to US health regulator FDA banning imports of drugs made at the facility.

According to the report released by the US Food and Drug Administration (FDA) inspection teams, as many as eight lapses were identified, including "Too Numerous To Count (TNTC) flies" in sample storage room, inadequate control over samples and non-adherence of procedures in sample analysis, during their visit to the Toansa, Punjab facility.

Other lapses included usage of un-calibrated and unqualified instruments in laboratory, said the report, which was released two days ago.

"Our inspection of QC Analytical and Microbiological laboratories found the facility to be in significant disrepair. Laboratories windows within the instrumentation (eg: HPCL) rooms were found to be un-closeable.

"Too Numerous To Count (TNTC) flies were observed throughout the sample preparation room, and laboratory reagent/equipment/documentation storage cabinets were found to be broken and un-closeable," FDA inspection report said.

Earlier this week, FDA banned the import of Ranbaxy products from its Toansa plant, halting the shipment of all the company's drugs to the US from India.

This is the company's fourth plant to face regulatory action from the American health regulator after Mohali, Paonta Sahib amd Dewas plants.

Citing manufacturing norm violations, the US Food and Drug Administration (USFDA) prohibited Ranbaxy Laboratories from distributing drugs produced at the Toansa unit, including medicines made by the company's Ohm Laboratories facility in New Jersey.

Expressing disappointment over the FDA ban, Ranbaxy had said it will cooperate with the FDA and "comply with Consent Decree in both letter and spirit".

The FDA inspection report further said that the Indian drug maker repeated the same errors which were cited by the regulator in its earlier inspection in December 2012.

"Appropriate controls are not established over computerised systems... This is a repeat observation from the previous FDA inspection in 12/2012.

"Specifically the standalone computerised system controlling GC# 6 does not have sufficient controls to prevent unauthorised access to, changes to, or omission of data files and folders," the report said. The audit team said that the raw material, intermediatesand finished API (active pharma ingredients) analytical results found to be failing specifications or otherwise retested until acceptable results are obtained. These results are not reported.

The FDA notice said Ranbaxy is required to hire a third- party expert to thoroughly inspect the Toansa facility and certify to the FDA that the facility and its methods and controls are adequate to ensure continuous compliance with cGMP (Current Good Manufacturing Practices).

"Ranbaxy will not be permitted to resume manufacturing and distributing API for FDA-regulated drugs from the Toansa facility until the agency is satisfied that Ranbaxy has addressed its manufacturing quality issues at that facility," it further said.

Regulatory