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GMP violation leads US FDA to warn two Indian firms

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Singapore: Indian drug makers Promed Exports and Post Chemicals have been issued a warning letter from US FDA for violation of good manufacturing practices (GMP). This is the sixth time the US drug regulator has taken action against an India-based drug making facility in the last three months.

The Hyderabad-based bulk drug company, Posh Chemicals, has also been accused of fudging data. Post investigations at the company's manufacturing unit, the FDA found problems like failure to protect computerized data from unauthorized access, failure to ensure that test procedures are scientifically sound and failure to follow and document, quality-related activities at the time they are performed. Based on their findings, the US FDA said that lapses found at the manufacturing facility may cause the active pharmaceutical ingredients (APIs) manufactured by the firm to get adulterated.

On the other hand, the FDA said that Sentiss Pharma (or Promed Exports) failed to establish adequate systems for monitoring environmental conditions and for cleaning and disinfecting the room and equipment in aseptic processing areas. The regulator has further claimed that the company failed to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications.

The FDA has now decided to withhold approval of any new applications or supplements of the two companies, until they put in place necessary corrective measures and get those corrections approved as per the US regulations.

Earlier last month, Wockhardt and Fresenius Kabi were issued warning letters by the FDA on related claims, while RPG Life Sciences and Hospira Healthcare India received warning letters in May.