

FDA issues warning letter to China API plant

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Singapore: The Food and Drug Administration has recently issued a warning letter to China-based Novacyl Wuxi Pharmaceuticals that manufactures active pharmaceutical ingredient (API). The agency, during its recent inspection of the facility, found non-compliance with the way the facility was keeping and tracking testing data.

FDA's letter raised questions about whether the company's procedures and products met FDA standards. Inspectors reported finding a chromatogram for a particular API in the trash that showed a deviation from the standard. The company indicated that it was thrown away because it was already in the computer system but then couldn't produce that test result because it had been overwritten.

The agency also noted that the Wuxi based plant had changed integration parameters for impurities test, without adequate documentation of justification. FDA also mentioned issues with data integrity and lack of written procedures for certain important tests.

Though Chinese manufacturers have dominated the market for its cheap APIs, the country has faced repeated quality hurdles. The FDA had established an office in China to facilitate facility inspections and offer training and expertise to the China's API plants.