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Singapore: After a recent inspection of Hospira's Melbourne based facility, FDA has labelled the pharma giant's drugs as 'adulterated'. Recently the regulator had slapped the drugmaker with a warning letter for serious failings of regulatory compliance and significant violations in the process of manufacturing injectable drugs used in hospitals.

Last year, an inspection conducted by Australia's Therapeutic Goods Administration unraveled similar deficiencies, however, the local body allowed Hospira to continue manufacturing, pending ongoing corrective actions. "Hospira Mulgrave was last inspected by the TGA in November, 2012. Deficiencies, including those cited in the FDA warning letter, have previously been observed by the TGA and notified to the company for action," a Department of Health spokeswoman said in a statement to The Australian.

In its warning letter the FDA had said, "The firm lacks corrective actions. There is gross failure to establish written procedures for production and process control to assure that the drug products you manufacture have the identity, strength, quality, and purity they purport or are represented to possess."

Hospira's local facilities are a crucial part of the Australian health system with all hospitals using its medicines. Hospira supplies 100 per cent of the morphine used in Australia and 15 per cent of all sterile injectable medicines used in Australian hospitals.

The Melbourne facility supplies injectables to 70 countries and was acquired in 2007 from Mayne pharma. The firm acknowledged the receipt of the warning letter and said that the letter did not restrict production or shipment of materials.