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Pharma exports face stricter scrutiny

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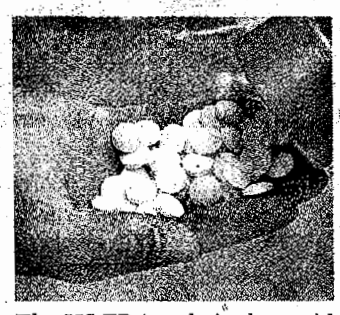
MUMBAI: The increasing popularity of Indian generic drugs in developed markets such as the U.S. has seen the US Food and Drug Administration (FDA) increase scrutiny of the quality of Indian medicines. The USA accounts for 30 per cent of India's pharmaceutical exports of $ 13 billion and is growing at 18-20 per cent.

Recently, Indian pharma major, Sun Pharmaceuticals recalled several bottles of Metformin HCL, used to treat Type 2 diabetes, after a customer complaint found tablets of Gabapentin, an anti-epilepsy drug in the bottle. Sun began recalling bottles from January 28, 2014.



The US FDA website has said that 2,528 Metformin HCL bottles were recalled.

In end-January, US FDA banned imports from Ranbaxy's Toansa plant making it Ranbaxy's fourth plant to face such action after Mohali, Poanta Sahib and Dewas. D.G. Shah, Secretary General, Indian Pharmaceutical Alliance (IPA) said Indian companies account for 12 per cent of warning letters by US FDA.

More vigilance

India is the largest exporter of generic drugs to US and with 135 US FDA approved plants, has the highest FDA-approved plants outside the US. Since setting up office in Delhi in 2009, followed by Mumbai and Hyderabad, the FDA has increased vigilance, conducting site inspections at short notice.

Gaurang Shah, Vice President, Geojit BNP Paribas, said "there was a feeling that Indian companies are being targeted but when making life saving drugs, the products and facilities have to meet stringent norms. After all, no Indian company has contested the US FDA."

exports.