

IV fluids recalled from five states, alert to others

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INFRAVITENOUS (IV) fluid bottles sold by Paracental Surgical Limited (PSL) have been recalled from five states even as the Indore-based company maintained that it was premature to blame its products for the deaths of pregnant women in a Jodhpur government hospital.

The IV fluids sold by the company have come under the scanner after 12 pregnant women died in the government-run Umaid Hospital in Jodhpur in 10 days. The deaths have been blamed on

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Premature to blame our products for Jodhpur deaths, says company

"infected" intravenous fluids. Manufactured in two batches in December and January, more than 45,000 bottles of dextrose and ringer lactate fluids were sold in Punjab, Orissa, Jharkhand, Rajasthan and Madhya Pradesh.

"We have asked dealers to immediately stop the sale of the remaining bottles and send them back. But 60 to 70 per cent bottles have already been used," PSL Director Manoj Khandelwal told The Indian Express.

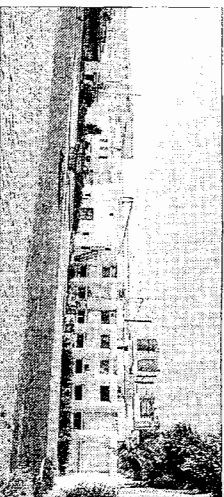
Khandelwal said the source of contamination could be anything from the needles to IV kits to injections. "The same IV fluids were used in the ward adjacent to where the deaths occurred as also in other states but nobody complained about them before," he said.

A two-year-old company with a turnover of Rs 40 crore, PSL only markets IV fluids manufactured by Paracental Drugs India Limited (PDIL), an old company with presence even outside India.

Drug inspectors based in Indore raided the manufacturing premises on Friday and sealed control samples, which are kept aside from every batch because products from both batches had been dispatched.

Between 1,200 and 1,500 samples from every batch are reserved as control samples. The company said a batch normally consists of 23,000 to 24,000 bottles.

The company claimed the control samples were tested on animals such as rabbits, as



The Indore unit where the IV fluids were manufactured

is the normal practice, before they were sent. Products are dispatched only a week after they are manufactured and tests are carried out during that period.

A team of four drug inspectors checked the manufacturing facility in the presence of a representative from the Drug Controller General of India.

Madhya Pradesh Health Secretary S R Mohanty said the samples sealed on Friday would be tested in a lab in Bhopal. He said some of the unsold bottles in Bhopal

were also seized from two locations. By late Friday, the authorities had seized 1100 out of the 1500 bottles sold in Bhopal.

The government said production at the Indore facility was not ordered to be stopped because there was no conclusive proof of contamination as yet.

Health Commissioner Manohar Agnani said fax messages were also sent to Bihar, Puducherry and Maharashtra where the product was supplied by the same manufacturer.

Meanwhile, the Rajasthan police said though they have

begun investigations in Jodhpur and Indore, a team has been sent to Rajasthan Drugs Control Organisation's (DDCO) Jodhpur Additional

intendent of Police Sharma said: "We proceed only on the basis that the IV samples tainted. The DCO has sent samples to Kolkata can proceed only once the report."

A DCO official said would get the report in days. "If the results show tampering, we can proceed with the drug manufacturer

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