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The US Food and Drug Administration (FDA) has started recalling a batch of two antibiotics, Cefotaxime and Amikacin following the use of which 18 children allegedly suffered adverse reactions at a Bhiwandi hospital. The department is also investigating for any local contamination.

Children between two and seven years of age complained of fever, cold, spasms and irritation after being administered a cocktail of Cefotaxime and Amikacin at the state-run Indira Gandhi Memorial Hospital (IGM). Some also started vomiting and developed breathing difficulties and needed oxygen support. The hospital said both medicines were within their expiry dates.

Besides the FDA, the local health department also began an investigation of the quality of samples.

"So far we have not heard of any complaints related to the batch from other places," an FDA official said. He added, "We have given orders to cease its use."

The FDA also sent samples for testing. At least four children, who were suffering from pneumonia and had suffered the adverse effects, were still hospitalized.

Independent experts hinted at local contamination, either of the syringe or the vials.

"Amikacin is a fairly safe drug and adverse effects are a rarity," Dr Mukesh Agrawal, head of pediatrics at KEM, said. He said, "Even for Cefotaxime, one in 10,000 children may suffer from reactions. Only local contamination or improper storage conditions can explain the incident."

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