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Sun Pharma recalls over 4 lk bottles of US drugs

New Delhi

Drug major Sun Pharmaceuticals is recalling over 4 lakh bottles of anti-depressant and anti-allergy drugs in the US for failing to meet specifications.

The recalls of anti-depressant Venlafaxine Hydrochloride extended release tablets of different strengths and anti-allergy Cetirizine Hydrochloride chewable tablets are being made by Caraco Pharmaceutical Laboratories, the US arm of Sun Pharma.

The company is recalling 1,28,363 bottles of Cetirizine Hydrochloride chewable tablets of 5 mg strength and another lot of 47,813 bottles of the same drug of 10 mg dosage prescribed for children, according to information on the US Food and Drug Administration website.

"Stability testing found the product may not meet the drug release specification through expiry," the FDA said. The recall of the anti-allergy medicine, which started on April 9, is under class III, defined as "a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences."

Caraco is also withdrawing two lots of anti-depressant Venlafaxine Hydrochloride as "stability results found the product did not meet the drug release dissolution specifications."

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