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Wockhardt's BP, antibiotic drugs recalled in the US

PRESS TRUST OF INDIA

New Delhi, June 5

Over 200 bottles of Captopril used in treatment of blood pressure and antibiotics Clarithromycin tablets manufactured by Wockhardt are being recalled in the US due to deviations in current good manufacturing practice norms laid down by US health regulator.

According to information on the US Food and Drug Administration (USFDA) website, 166 bottles of Captopril tablets of 50 mg strength are being recalled in the US.

In case of Clarithromycin, the recall is for 50 bottles containing tablets of 500 mg strength.

The recall is made by Blenheim Pharmacal Inc, which packages and repackages Captopril and Clarithromycin, respectively. The USFDA said the reason for the recall is cGMP (current good manufacturing practice) deviations and current good manufacturing practice. In both the cases, the products are being recalled "in response to a recall notice from the manufacturer, Wockhardt Ltd, following a FDA inspection which noted inadequate investigation of market complaints, resulting in unsuccessful identification of root causes, and the investigation not being expanded to prevent repeat failure", it added.

The recall is made by Blenheim Pharmacal Inc, which packages and repackages the two drugs

Both the recalls are classified as Class II, "a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote".

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