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# HYDERABAD-BASED BHARAT BIOTECH RECALLS TYPHOID VACCINE BATCH OWING TO SUBSTANDARD QUALITY

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The recall was initiated utilising the principle of abundant precaution based on test results of field samples. File image for representation | Photo Credit: Reuters

Flagged by the Central Drugs Standard Control Organisation (CDSCO) as “not of standard quality’’, Hyderabad-based Bharat Biotech on June 8 confirmed that it had recalled a batch of its typhoid vaccine.

CDSCO officials found that a batch manufactured at the Hyderabad facility did not comply with the standard specification of the drug controller. While the company in its statement, said that there were no reports of adverse events or safety issues due to the batch in the country, it added that a recall had been initiated.

“Bharat Biotech has initiated a recall of TYPBAR batch 54A22001A (vi polysaccharide typhoid vaccine) and communicated the same to the distribution chain,” a Bharat Biotech statement said.

It added that the recall was initiated utilising the principle of abundant precaution based on test results of field samples by the Central Drugs Laboratory.

According to an alert by CDSCO, the samples of the vaccine by Bharat Biotech were drawn by the Food and Drug Administration (FDA), Goa and tested by the Central Drugs Laboratory (CDL), Kasauli, Himachal Pradesh.

The TYBPAR typhoid vaccine from Bharat Biotech is the first vaccine in India to get a World Health Organisation Good Manufacturing Practice (WHO-GMP) pre-qualification certificate and is currently sold in more than 50 countries, according to the company.



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