

## Medicines had expired by the time we got regulator's alert: Abbott

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Pharmaceutical company Abbott has said the batch of its epilepsy drug Mazetol SR 200, which the drug regulator had found to be sub-standard last December, had already expired in October. Therefore, no analytical testing was possible on the expired product, it told *Business Standard*.

The company said it verified the manufacturing records of this batch and found that it had followed all required standards and specifications.

"Records of the same were submitted to the authorities along with detailed response on the government test report," said an Abbott spokesperson in response to queries from *Business Standard*. Moreover, as the batch had expired, it did not recall any drugs from the market which could have affected its financial health.

Mazetol SR 200 is an anti-convulsant drug, which is generally prescribed for epilepsy and bipolar disorder. Its molecule name is Carbamazepine. According to IMS Health, a global information and technology services company, Abbott sold ₹11.4 crore of Mazetol tablets in India in 2015-16.

The company received an alert from Gujarat's Food and Drug Administration in December that a batch of Mazetol SR 200 tablets, which were manufactured in November 2013, had failed to pass the dissolution test. This test determines the rate at



No analytical testing was possible on the expired batch of the epilepsy drug, Mazetol SR 200, Abbott said REUTERS

which the drug gets dissolved in the blood stream after its ingestion.

The batch was manufactured in the company's Vapi plant in south Gujarat. The dissolution test was done by the Central Drugs Standard Control Organization at its regional laboratory in Kolkata.

The total annual sales of the molecule Carbamazepine in India was estimated at ₹113 crore in 2015-16. Novartis dominates the market in this molecule — it has issued seven different brands and has almost 60 per cent market share, according to IMS Health. The other major companies manufacturing and selling this molecule in India are Sun Pharma, Intas Pharma, Micro Labs, Torrent Pharma, etc.

Meanwhile, the latest drug to be recalled from the market is four batches of Combiflam, the popular pain killer from the stable of French pharma company Sanofi.

Company