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Drugs made amid filth

USFDA finds many Indian pharma firms with swanky offices produce drugs in messy conditions

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Bloomberg

THE Indian factory that makes copies of a popular heart pill sold in the US turns out to be a jumble of dilapidated buildings with blighted windows connected by flaking pipes and capped by a rusty roof.

When US Food and Drug Administration inspectors visited the Wockhardt plant that produces generic copies of the heart tablet Toprol-XL in July, they found urine spilling over open drains, soiled uniforms and mold growing in a raw-material storage area. They summarised their findings in a filing obtained via a Freedom of Information Act request.

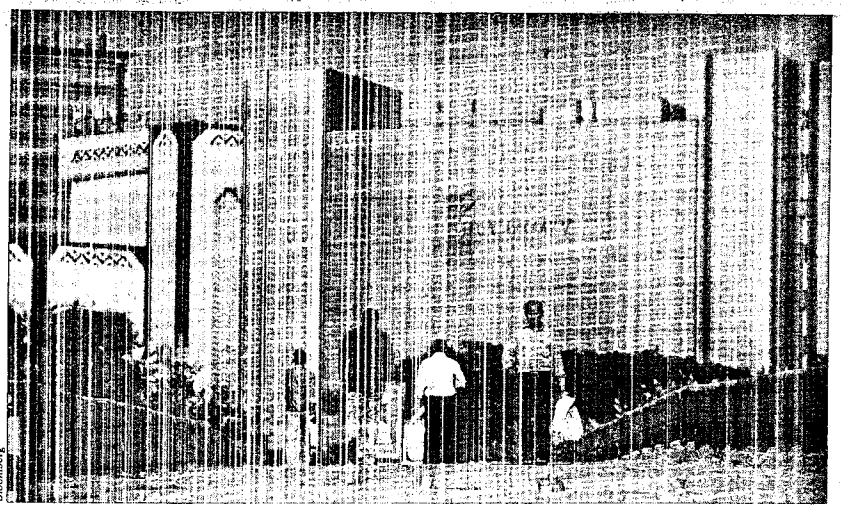
The document, known as an FDA Form 483, listed 16 so-called observations about Wockhardt's factory in Chikalthana, 200 miles east of Mumbai, including concerns about quality control. While the FDA isn't commenting on the possibility of enforcement action, such forms can be a prelude to export restrictions. A typical one contains only four to eight entries, said John Avellanet, managing director of Cerulean Associates, an FDA compliance consultancy in Williamsburg, Virginia.

"This is very serious," Avellanet said in an e-mail after reviewing the document. "Think of it as a giant vote of 'no confidence' from the FDA."

Wockhardt fell to Rs 549.85 at in Mumbai, the most since September 17.

"Wockhardt's down because its biggest product comes from this facility," said Prakash Agarwal, an analyst at CIMB Securities India in Mumbai. "That will be a big overhang on the stock."

As US regulators step up inspections, they're finding more examples like Wockhardt's. The FDA has filed reports on four Indian facilities in the past six months and curbed exports at two drugmakers, including Ranbaxy Laboratories the country's largest. The findings highlight the contrast between immaculate headquarters like Wockhardt's in Mumbai and working conditions at remote locations in India, where a fifth of the world's generics are made.



Bloomberg

FILTHY RICH: Wockhardt at present controls about 26 per cent of the US market for that pill, according to Needham. Metoprolol alone makes up about 14 per cent of the company's Rs 5,600 crore in annual revenue

Wockhardt's Chikalthana plant makes metoprolol, a generic version of the heart pill sold by London-based AstraZeneca under the brand name Toprol-XL. The white copycat tablets with beveled edges were approved for sale in the US in July 2010 and belong to a class of medicines called beta blockers, which make the heart beat slower and with less force.

Wockhardt currently controls about 26 per cent of the US market for that pill, according to Needham. Metoprolol alone makes up about 14 per cent of the company's 55 billion rupees in annual revenue. About $1.1 billion of generic Toprol-XL tablets are sold in the US by companies including Watson Pharmaceuticals and Par Pharmaceutical, data compiled by Danbury, Connecticut-based IMS Health show.

The FDA's mandate includes inspecting overseas drugmakers cleared to sell medicines in the US to monitor safety. The agency didn't report finding contaminated pills. The Chikalthana filing marks the second time this year the regulator has noted diversions from what it calls current good manufacturing practices at a Wockhardt factory. The facility was intended to serve as a production backup after the FDA issued a warning letter in July about the company's plant in Waluj, near the industrial city of Aurangabad.

> Toilets had inadequate drainage piping with urine found falling directly on the floor

The FDA curbed the Waluj plant's right to export to the US, saying Wockhardt's response to a Form 483 lacked sufficient corrective action. The inspectors noted seven observations at Waluj, less than half the total for Chikalthana.

Ranbaxy, India's largest drugmaker, had a third plant banned from exporting drugs to the US last week. Another drugmaker, Strides Arcolab said last week a facility in Bangalore being bought by Mylan got a warning letter after an inspection in June.

Wockhardt has hired consultants, appointed a new quality supervisor and is working on a better compliance system to address the report on Chikalthana, it said in a response to questions e-mailed by the public-relations firm Ketchum Sampark.

The FDA carried out the Chikalthana inspection from July 22 to July 31 jointly with the Irish Medicines Board and UK Medicines and Healthcare Products Regulatory Agency, which said in an e-mailed response to questions that it, too, identified "a number of manufacturing issues."

The FDA's 10-page report on Chikalthana notes missing and undocumented drug samples and an instance in which a worker didn't record observed values during testing, instead stating he could remember the figures "in his head."

A check of the linen room found worker uniforms crusted with dirt. Raw-material storage areas had "significant mold growth" and the men's toilets and toilets for the manufacturing gowning areas had urinals with inadequate drainage piping, with urine found to fall directly on the floor where it was collected in open drains and causing an odor, according to the report.

Inspectors found tablets stored at the wrong temperature, raw materials and finished drugs kept in makeshift storage areas with no cleaning or temperature procedures, and condensate droplets falling from an overhead air handling unit onto shipping containers of pills, they wrote. They also expressed concern about quality control procedures, mentioning "multiple examples" in which "samples appeared to have been tested into compliance."

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- As US regulators step up inspections, they're finding more examples like Wockhardt's
- Findings highlight the contrast between working conditions inside major cities and remote locations

Regulatory