# Sun Pharmaceuticals | SUNP IN

Price: ₹821

## Surprise checks shouldn't really surprise

**The USFDA is conducting a surprise inspection at Sun's Halol plant. While an inspection in 2014 was expected, the timing of it is slightly earlier than anticipated. As per FDA guidelines, if the plant goes beyond inspection for >2 years it becomes eligible for an audit and since the plant was last inspected in Sep '12, an inspection was around the corner. At this stage though the problems are not in the public domain, we are comfortable with Sun's ability to handle manufacturing/regulatory issues with respect to developed markets.**

- **Halol facility undergoing a surprise check by USFDA:** Newswires have reported that Sun Pharma's Halol facility is undergoing a surprise inspection since Monday by a team of 5 FDA inspectors. According to the news articles, FDA inspectors in two teams are auditing the injectables as well as oral solids units, with one team focusing on manufacturing processes and other auditing quality control and assurance departments.
- **Background on Halol:** Halol unit is the biggest contributor to US (ex-Taro). Of the 10 FDA-approved formulation manufacturing sites, 2 are based in India, of which Halol is the biggest. In the past few months there have been product recalls of venlafaxine hydrochloride (40,000 bottles of XR tablets in Jul '14 as did not meet the drug release dissolution specifications), Gemcitabine (200 vials due to a lack of assurance of sterility) and Metformin XR (2,528 bottles when a customer complained that one of the bottles contained tablets of epilepsy drug Gabapentin).
- **Background on surprise inspection in India:** India being the 2nd largest generics supplier to the US, the FDA scrutiny has gone up in recent years. The new GDUFA rules said that the FDA conduct similar number of inspections in both US & foreign facilities. In 2013, FDA increased its staff from 12 to 19 and also planned to conduct surprise checks. Earlier, FDA's inspections of Indian pharma plants had always been with prior notice. The surprise checks were considered because of instances of fabrication of documents and human error in Indian manufacturing units. According to Bloomberg, FDA had also conducted a surprise visit to Ranbaxy's Toansa facility in January.
- **Was the FDA inspection a complete surprise?** While we had expected an inspection in 2014, the timing of it was slightly earlier than anticipated. As per FDA guidelines, if the plant goes beyond inspection for >2 years it becomes eligible for an audit and since the plant was last inspected in Sep '12, an inspection was around the corner. In our view, what may have lead to an earlier than expected inspection besides the product recall was the Karkhadi plant warning letter (May '14) which had asked the company to expand its "internal review to any other facilities involved in, or affected by, inaccurate data reporting."
- **What next - assuming a Form 483: For Sun:** Historically Halol plant has not fallen afoul of the regulatory agencies. Assuming a worst-case that FDA does issue a Form 483, we would expect a negative impact on revenue as well as margins as as the leverage of Halol plant to the overall profitability is high. At this stage though the problems are not in the public domain, we are comfortable with Sun's ability to handle manufacturing/regulatory issues with respect to developed markets. **For Indian pharma:** Going forward, we believe that FDA may continue with surprise checks at Indian pharma facilities. The FDA and its Indian counterpart had reached an agreement in Feb whereby the latter would be kept in the loop and also join inspections as observers. However, it doesn't allow the Indian regulator to inform the

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company in advance of the FDA's inspection plans in order to retain the surprise element of such inspections. We believe this may actually benefit a company like Sun which has demonstrated a good regulatory track record vis-a-vis some of it's peers.

**Exhibit 1. US FDA inspections for major Indian Pharma companies since Jan '13**

| Company | Facility | Date | Action |
|---|---|---|---|
| Sun Pharma | R.C. Patel estate, Baroda | Nov '13 | 483 issued |
| | Tandalja, Baroda | Nov '13 | No 483s issued |
| | Karkhadi, Baroda | Nov '13 | Import Alert issued |
| Dr Reddy's | Princeton, NJ | Dec '13 | No 483s issued |
| Cadila | Moraiya, Ahmedabad | Aug '13 | 483 issued |
| | Baroda | Mar '13 | 483 issued |
| Cipla | Verna, Goa | Sep '13 | No 483s issued |
| | Verna, Goa | May '13 | 483 issued |
| | Pithampur, Dhar | Feb - Mar '13 | 483 issued |
| Lupin | Verna, Goa | May '13 | No 483s issued |
| | Baroda | Jan '13 | No 483s issued |
| Torrent | Indrad, Gujarat | Jul '13 | 483 issued |
| | Bhat, Gujarat | Mar '13 | 483 issued |
| Ipca | Pithampur, Dhar | Apr '13 | 483 issued |
| Glenmark | Indore | Oct '13 | 483 issued |
| | Goa | Sep '13 | 483 issued |
| | Goa | Jul '13 | 483 issued |
| Ranbaxy | Taonsa | Jan '13 | Import Alert issued |
| | Mohali | Dec '12 | Import Alert issued |
| Aurobindo | Unit I, Hyd | Nov '13 | No 483s issued |
| | Unit V, Hyd | Oct '13 | No 483s issued |
| | Unit XII, Hyd | Aug '13 | No 483s issued |
| | Research centre, Hyd | Jul '13 | No 483s issued |
| Alembic | Unit I Panchmahal | Apr '13 | 483 issued |
| | Unit II Panchmahal | Apr '13 | 483 issued |
| | API Unit III, Baroda | Apr '13 | 483 issued |
| Indoco | Plant II & III, Goa | Aug '13 | 483 issued |
| Unichem | Dhar | Apr '13 | 483 issued |
| Divi's/ Natco/ Biocon | No inspections since Jan '13 | | |

Source: FDAzilla, JM Financial

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