The USFDA’s inspection of Sun Pharma’s Halol plant recently (December 3-13, 2019) resulted in eight observations. This is the third inspection at Halol in 2019 (the first was in Feb’19 and then in June ’19, both classified NAI/VAI). We accessed the 483 letter and believe that almost all observations - barring Observation No. 1 and Observation No. 2 - are procedural in nature. There is one repeat observation (Observation No. 4). Observation No. 1 relates to OOS products, while Observation No. 2 highlights the lapses in processes to ensure complete data integrity. Both of these will require a rather comprehensive explanation/response, in our view.

Halol accounts for 10-12% of the overall US business. Although the number of filings from the plant are unknown after the warning letter earlier, quite a lot of filings would have been transferred to other sites and thus, the financial impact may not be meaningful even if the observations escalate. Nevertheless, this would be a sentiment dampener in the interim.

The observations are as below:

**Observation No. 1** relates to out of specification products. The FDA has pointed out instances where the root cause and OOS source are not properly identified.

**Observation No. 2** is a slightly tricky one. The FDA pointed out inadequate controls to ensure data integrity in the use of environmental monitoring computerized system. Specifically, the regulator highlighted issues with the review of audit trails, a lack of CAPA to reduce the re-occurrence of identified trends and privileges to supervisors to edit all microbiological test results in the system without prior authorization from Sun Pharma’s management.

In addition, the FDA pointed out failures to ensure data integrity in raw material dispensing with instances of dispensing date missing on containers, employees documented as dispenser not dispensing the raw materials, etc.

**Observation No. 3** is the failure to establish scientifically sound and appropriate analytical test procedures. The FDA highlighted that representative sample vials used to perform analytical tests are not conforming to expected quality attributes.

**Observation No. 4** is the lack of adequate procedures/instructions during sampling process. This is a repeat observation.

In **Observation No. 5**, the FDA pointed out a lack of documented evidence that demonstrates the environment monitoring conditions in the aseptic processing areas.

In **Observation No. 6**, control procedures not established to monitor the output in the manufacturing process. The FDA pointed out that training to quality inspectors was not verified to test their ability to check critical defects.

In **Observation No. 7**, the FDA highlighted inconsistencies in terms of the time spent on manual visual product inspections by quality inspectors as the written procedures do not sufficiently describe them.

In **Observation No. 8**, the FDA pointed out that there was no comprehensive assessment to identify the source for alarmed events. Usually, in the manufacturing process, alarms are used to indicate equipment malfunction or abnormal temperature conditions.

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Completed Date: 20 Dec 2019 12:27:44 (SGT)
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