DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| Food and Drug Administration/ORA/OPQO/HQ<br>12420 Parklawn, Room 2032<br>Rockville, MD 20857<br>Attn: Atul Agrawal;orapharminternationalresponses@fda.hhs.gov<br>Industry Information: www.fda.gov/oc/industry | 7/8/2024 - 7/12/2024 |
| | FEI NUMBER<br>3010956224 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Mr. Weiwei Xu, General Manager

| FIRM NAME | STREET ADDRESS |
|---|---|
| Hisun Pharmaceutical (Nantong) Co., Ltd. | No.18, 4th Haibin Road, Rudong Coastal Economic Development Zone |
| CITY, STATE, ZIP CODE, COUNTRY<br>Nantong City, Jiangsu Province, China | TYPE ESTABLISHMENT INSPECTED<br>API Manufacturer |

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM, WE OBSERVED:

**OBSERVATION 1**

**Changes to written procedures are not reviewed and approved by the quality control unit.**

Specifically,

[redacted] (b) (4) were introduced to the in-process sampling area in the production of [redacted] (b) (4) This introduction of a new sampling device was not evaluated or covered by a change control. Your firm discovered the negative interaction of the [redacted] (b) (4) due to an unknown impurity peak appearing in the cleaning rinse samples of cleaning batch [redacted] (b) (4)

**OBSERVATION 2**

**Deviations from written process control procedures are not recorded or justified.**

Specifically,

Deviation investigations are not conducted to identify all root causes and/or implement corrective actions to prevent reoccurrences. Several CAPAs were enacted to train and retrain operators on the proper sampling technique involving sample bottles. However, the training was only given to operators in the impacted area, not all employees involved in sampling. Therefore, repeat deviations occurred involving sampling errors and retraining of operators:

a. CAPA D-NT-[redacted] (b) (4) 22004
   i. Trained operators on H8-SOP-65001-14

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ii. Sampling bottles must be cleaned in accordance with the SOP

b. CAPA D-NT-QC-23010
   i. Train workshop personnel with H8-SOP-65001-14
   ii. Emphasize sampling cup should be (b) (4) before sampling

c. CAPA D-NT-(b) (4)24001
   i. Update H8-SOP-65001-14 to add 'confirm cup is (b) (4) before sampling'
   ii. Training workshop personnel cup should be (b) (4) before sampling
   iii. Train all employees on sampling tools

**OBSERVATION 3**

**Equipment and utensils are not cleaned or maintained at appropriate intervals to prevent contamination that would alter the strength, identity, safety, strength, quality, or purity of the drug substance.**

Specifically,

There is no assurance that your firm's production equipment is properly maintained in order to prevent it from becoming a potential source of contamination of the intermediates and manufactured substances using equipment, for example:

a. (b) (4) 4053-6-2 was observed to have a worn and frayed (b) (4) gasket, with notable pieces missing. This (b) (4) was also observed to have an apparent (b) (4) piece of foreign material, approximately 1-2" large, located inside the equipment. This piece of equipment was listed as in a "cleaned" status.

b. (b) (4) 4042-6-2 was found with apparent (b) (4) residue, and a worn gasket with pieces missing. This piece of equipment was listed as in a "cleaned" status.

c. (b) (4) 4053 was observed to have a (b) (4) piece of unknown material on the bottom of the (b) (4) (b) (4) This piece of equipment was listed as in a "cleaned" status.

**OBSERVATION 4**

**There is a failure to establish adequate written procedures for cleaning equipment and its release for use in the manufacture of intermediates and APIs**

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Specifically,

Your Cleaning Operation SOP for (b) (4) H8-SOP-44001-01, does not include instructions for visual inspection, such as looking for foreign material, use of a flashlight, or a second verification of visibly clean equipment.

APPEARS THIS WAY ON ORIGINAL

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