DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Food and Drug Administration, CDER/OC/OMPQ/DIDQ HFD-325 10903 New Hampshire Avenue, Building 51, Room 4225 Silver Spring, MD 20993 PH: +1-301-796-3334 Fax: 1-301-847-8738 Industry Information: www.fda.gov/oc/industry	4/18-22/16
	FEI NUMBER 3006512854

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Naishan (NMI) Liu, Chairman & Founder

FIRM NAME	STREET ADDRESS
Qingdao Kangyuan Pharmaceutical Co., Ltd.	No. 3 Yinghai Industrial Area, Jiaozhou City
CITY, STATE AND ZIP CODE Qingdao 266300, China	TYPE OF ESTABLISHMENT INSPECTED 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 (I) (WE) OBSERVED:

Observation # 1.
During the previous inspection on 1/25/2013, it was found that no study protocol had been generated for impurity profile characterization of (b) (4) It had been stated in the firm's response of 3/1/2013 that a draft protocol would be submitted to the FDA in 1-2 months. During the current inspection, although your firm presented some draft data (not in English), but your firm did not produce a conclusive impurity summary results in English. Further, your firm stated that as of date, no response has been submitted to the FDA as the impurity studies are still in-progress.

Observation # 2.
During the previous inspection on 1/25/2013, it was found that the (b) (4) results from the (b) (4) were noticeably different (b) (4) According to your firm's response, these different (b) (4) are within range and do not impact the product quality. According to our conversation, you have added another (b) (4) but none of these (b) (4) have been qualified to assure that its (b) (4) is accurate, precise, linear, and robust.

Observation # 3.
During our walkthrough of the Building (b) (4) which is used for (b) (4) API production, your firm explained that the HVAC, ID #SC-KTJ-12-01, for clean rooms class D is powered off during non-operation. It was further explained that the HVAC power is turned on for (b) (4) during non-operation. Since the HVAC system is re-qualified (b) (4) and was last re-qualified on 7/12/2015, no data was presented as to its qualification status when the system is powered off and only powered on for (b) (4) during non-operation.

Observation # 4.
The firm explained that the (b) (4) used during (b) (4) step is replaced according to the manufacturer (b) (4) Since the qualification of the (b) (4) none of the (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Debra I. Love Saied A. Asbagh	Debra I. Love, Investigator Saied A. Asbagh, Investigator	4-22-16

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(b) (4) replacement frequencies are specified in the maintenance schedule and it is unclear how the replacement will occur in the batch record instructions.

Observation 5.
The (b) (4) of the (b) (4) water system is not monitored and no (b) (4) are installed throughout the system. There is no (b) (4) indication of the (b) (4) water distribution tank and the loop system to the building (b) (4) workshop.

Observation 6.
The firm has conducted bulk hold-time studies for the (b) (4) operations. The firm, however, did not produce bulk hold-time data for the (b) (4) crude, (b) (4) stages of the (b) (4) production.

Observation 7.
The scale, ID # SC-DZC-17-06, which is used in the (b) (4) room, is (b) (4) calibrated using a (b) (4) standard weight. However the scale weighing range is between (b) (4) to (b) (4) In addition the vendor calibration certificate dated (b) (4) did not indicate that the scale had been calibrated within the scale weighing range. The scale (b) (4) calibration does not cover the stated scale weighing range.

Observation 8.
On 4/18/16, we observed an electrical balance, ID # SC-DZC-17-04, and a container housing a (b) (4) reference weight, ID # SC-DZC-17-04, sitting on the floor of the (b) (4) Warehouse (b) (4) which may be subject to contamination and instability. The balance is used to check the weight of incoming (b) (4) raw materials after receipt by the warehouse.

Observation 9.
On 4/18/16, we observed an attachment form, titled " Balance using records 03-103-A1 02", which was used to record the weight of (b) (4) materials, (b) (4) Crude, on 4/2/16. The actual weight of each material is not recorded on the form. This form was found sitting on the floor of the (b) (4) Warehouse (b) (4) next to the electrical balance, ID # SC-DZC-17-04, and a container housing a (b) (4) reference weight, ID # SC-DZC-17-04.

Observation 10.

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The written procedure, Gauge and Calibration Management, SOP 03-103, version 02, effective date 7/20/15, did not include adequate instructions regarding where a balance should be placed for weighing and measuring operations. This procedure only states to place the instrument in a clean and dry environment. The procedure also does not have instructions regarding re-calibration of a balance after it is moved.

Observation 11.
On 4/20/16, during the walkthrough of the building (b) (4) Workshop, we observed (b) (4) stations situated on the exterior of the building which contained no (b) (4)

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