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/DMPQ/ICT, HFD-325 10903 New Hampshire Avenue, Building 51, Room 4218 Silver Spring, MD 20993 PH: +1 301 276-8261 ATTN: Ms. Elizabeth Philpy Industry Information: www.fda.gov/oc/industry	January 21-25, 2013 FEI NUMBER 3006512854

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Naishan Liu, President and General Manager

FIRM NAME	STREET ADDRESS
Qingdao Kangyuan Pharmaceutical Co., LTD	#3 Yinghai Industrial Area, Jiaozhou City
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Qindao, Shandong, China 266300	API Producer

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DURING AN INSPECTION OF YOUR FIRM (I)/(WE) OBSERVED:

1. From 12/10 to 7/12, quantities of (b) (4) finished batches of (b) (4) bearing a labeling for use in (b) (4) have been shipped to USA. The finished product shipped to the USA was tested based on the Chinese Pharmacopeia method. On December 27-31, 2012, a study was performed comparing only the potency method listed the Chinese Pharmacopeia with the USP (lot (b) (4) but no lot number of (b) (4) used were recorded.

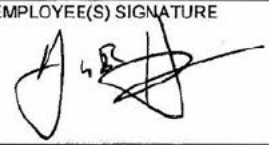
2. There is no written and approved stability study protocol. The three PV batches (b) (4) (b) (4) were reportedly placed on stability studies. However, the samples for these batches were initially stored in a refrigerator. The samples were moved from the refrigerator to two other stability storage study units, but there is no written explanation as to how, when, and why the samples were managed when moved out each of the stability study storage units.

3. There was no study protocol to for developing an impurity profile on the product nor there was an impurity profile on (b) (4) for review.

4. No forced degradation studies have been performed on (b) (4) produced at the current manufacturing site.

5. The contract laboratory performs the residual solvent test for detecting (b) (4) in the finished product. This test is reportedly performed in accordance with the Chinese Pharmacopeia method. There is no information to determine whether this method is equivalent to the USP <467> method. Also, there is no information to determine whether the Chinese Pharmacopeia method had been qualified by performing at least linearity and specificity with equipment used for testing. Moreover, (b) (4) is used in the process but neither the intermediate or the finished product is tested for this solvent.

6. The incoming (b) (4) solvent used in the process is not tested for purity/potency.

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7. The Crude product used to produce the finished product is produced by (b) (4) different suppliers. Reportedly, these suppliers do not have the capability of testing the crude product and the product is received untested. QKP tests the crude product. However, review of test records for the potency test performed found no data to allow traceability of lot numbers and expiration dates on reagents and solutions (i.e., standard solution, water, and (b) (4) used when the test is performed; for example, Crude supplier's lot # (b) (4) tested on 3/20/12.

8. (b) (4) type apparatuses used to (b) (4) the product in the '(b) (4) step,' generate noticeably different (b) (4) despite (b) (4) apparatuses being essentially the same. No investigation or experiment has been done to determine why the (b) (4) from these apparatuses look different.

9. The (b) (4) step requires the use of (b) (4) apparatus). It was reported that (b) (4) is fixed at (b) (4) but the (b) (4) has not been qualified to assure that the its (b) (4) is accurate, precise, linear, and robust. Also, the lot number of the (b) (4) use during the manufacturing is not documented; for example during the Processing of process Validation batches (b) (4)

10. The BPR does not document the duration of the (b) (4) step of the (b) (4) during production; for example, at the (b) (4) stage' the (b) (4) is (b) (4)

11. An entry in page (b) (4) of the BPR for the (b) (4) processing step documents that (b) (4) of the (b) (4) were collected and measured. However, while questioning this BPR entry, it was reported that the operator measures the amount of (b) (4) The measurement is done (b) (4) The actual steps as to how the operator came up with the (b) (4) value, documented in the BPR, are not documented in the BPR or explained in an operating instruction procedure.

12. SOP 10-103 requires QA to check and sample products that are returned to the site. However, there is no data to show that QA checked the amount of batch (b) (4) returned to the firm on 2/28/11 and 3/16/11, respectively. It was reported that this product was returned from the USA due to the product cost being too high. The product was accepted by warehouse personnel and returned to product release inventory.

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13. A physical inspection of the (b) (4) water system revealed the following:

- (b) (4) type valves were mounted (b) (4) in the water distribution line installed after the water (b) (4) storage tank. These (b) (4) valves were installed in such a way that may not allow for complete drainage.
- All valves observed at the use water use points are the (b) (4) valve type.
- The was a water leak at the connection of the tubing to a pressure gauge after the (b) (4)
- No TOC test is performed.

14. SOP 09-301 requires analytical balances to be placed on a vibration proof surface. However, inspection of the table used to hold Metter Toledo analytical balance #JY-TP-12-01 revealed that the table vibrated to the touch. Also, one of the legs of the table appeared to be shorter than the other 3 legs and was supported by what appeared to be a folded carton. Also, the (b) (4) check of the balance was performed using a (b) (4) mass grams weight when in fact the sample weight used in testing is in milligrams.

15. There was no identification, calibration record, or usage log on a scale found in the raw material weighing and dispensing room. Reportedly, this scale is used to weigh (b) (4) used in the product formulation and recorded in the BPR.

16. There were several undated loose pages of partially completed batch production records for processing stages (b) (4) steps) in a drawer of a desk in the office used by production operators and management.

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