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 10903 New Hampshire Avenue Bldg. 51, Room 4225 Silver Spring, MD 20993 Phone: 1-301-796-3206 Industry Information: www.fda.gov/oc/industry	July 8-12, 15-18, 2013
	FEI NUMBER 3003802432

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: LI Yan, General Manager

FIRM NAME	STREET ADDRESS
Qilu Pharmaceutical Co. Ltd.	No. 317 Xinluo Rd. High-Tech Zone
CITY, STATE AND ZIP CODE Jinan, Shandong, China 250101	TYPE OF ESTABLISHMENT INSPECTED Finished Drug Manufacturer

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

OBSERVATION #1

Your firm failed to ensure that laboratory records included complete data derived from all tests necessary to assure compliance with established specifications and standards.

Specifically, on July 11, 2013 the following environmental monitoring plates collected on July 5, 2013 were observed to contain microbial growth:

1. (b) (4) CFU, the sample was a settle plate in grade A area near the (b) (4) line of (b) (4) The action level for this location is (b) (4) CFU.
2. (b) (4) CFU, the sample was a settle plate from the grade B area in the (b) (4) room of the (b) (4) line of (b) (4) The action level for this location is (b) (4) CFU.
3. (b) (4) CFU, the sample was a settle plate from the grade B area in the (b) (4) room after (b) (4) of (b) (4)

The analyst had recorded 0 CFU for all three plates on the evening of July 10, 2013. All three original plates were destroyed on the morning of July 12, 2013, prior to the completion of an investigation.

Additionally, the procedure for reading plates does not require the analyst to open the plates when they are read and there is insufficient lighting in the room to properly view plates.

OBSERVATION #2

Your firm failed to establish and follow appropriate written procedures that are designed to prevent microbiological contamination of drug products purporting to be sterile, and that include validation of all aseptic and sterilization processes

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1. The following was observed during surface monitoring samples for the (b) (4) aseptic fill line collected as part of the environmental monitoring program on July 11, 2013:

A. When collecting the sample on the vial (b) (4) (grade A area) the operator sprayed the sample site with (b) (4) (b) (4) immediately before touching the plate to the surface.
B. When collecting the sample on the filling machine (b) (4) surface of filling machine # (b) (4) the operator opened the plate, held it close to the surface, but the (b) (4) never touched the surface.
C. When collecting the sample of the filling machine (b) (4) surface of filling machine # (b) (4) the operator only touched a portion of the (b) (4) to the surface.
D. During collection of all samples in the Grade A/B areas the operator never applied "… (b) (4) (b) (4) ..contacting for at least (b) (4) " as described in the SOP PO-5067O, "Procedure for Environmental Monitoring of Clean Area of Workshop No. 2".

2. Alert and action limits for the environmental monitoring system and (b) (4) system do not reflect historic data. It was reported there have been no investigations as a result of environmental monitoring in workshop # (b) (4) (b) (4) injection on (b) (4) different lines, since production began in (b) (4) used to fill

It was reported that an alert or action limit has never been reached during workshop # (b) (4) environmental monitoring, monitoring of the (b) (4) system in workshop # (b) (4) monitoring of the (b) (4) system in workshop # (b) (4) or monitoring of the (b) (4) system in workshop # (b) (4) during 2011, 2012, or 2013.

Limits have not been adjusted to reflect these results.

3. Smoke studies did not evaluate critical dynamic operations, some of which include:

A. Filling of vials.
B. Stoppering of vials.
C. Unloading the uncovered filling machine parts from the (b) (4)
D. Loading and unloading of uncovered filling machine parts from the (b) (4)
E. Set-up of the filling machine.

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4. For the performance of media fills:

A. Media fill batch records lacked documentation that all operators that perform interventions during routine production also perform the intervention during the media fill. For example, there is no documentation the (b) (4) manager changes the API canisters during media fills or that all personnel that can add stoppers during production, do so during the media fill.

B. Media fills do not adequately address operator fatigue. On 6/14/12 operators began set up at (b) (4) and filling at (b) (4) batches were filled during the (b) (4) And though there were breaks (b) (4) and (b) (4) during the (b) (4) the filling of the (b) (4) batch was not completed until (b) (4) on 6/14/12. Media fills cover a (b) (4) filling period.

C. The media fill batch records lacked documentation to demonstrate that vials are (b) (4) for (b) (4) prior to incubation as described in media fill procedure GR-1053H.

5. (b) (4) are installed into the filling barrier to perform interventions on the filling lines. The (b) (4) are handled extensively by the operators on their grade A surface during (b) (4) cleaning. They are never sterilized. They remain in place for (b) (4) The (b) (4) pass over exposed vials and product. They are used to perform the (b) (4) They are only part of the environmental monitoring program on the

6. There is no system in place to identify molds recovered during environmental monitoring. If the microbiology analysts visually observe colony morphology and determine the organism is likely a mold, there are no further identification steps.

7. The (b) (4) filling machine parts are not wrapped during (b) (4) After the (b) (4) process the (b) (4) equipment is transferred by operators from the (b) (4) to a (b) (4) laminar flow unit, passing through un-sterilized (b) (4) that could contact the unprotected equipment surfaces. It is then transferred by operators to a (b) (4) for holding. From the (b) (4) the equipment is transferred back into the (b) (4) laminar flow unit and then into the filling room by operators. During these transfers operators have the potential to contaminate unprotected equipment.

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8. Not all removable parts from the fill line are sterilized. For example, the tools used to perform the line set-up are not removed from the filling line for sterilization.

OBSERVATION #3

Cleaning of equipment does not ensure there is no cross contamination.

1. The (b) (4) duct for the (b) (4) has a (b) (4) valve between the product contact (b) (4) side of the duct work and the "HEPA filter" side of the duct work. The valve is to remain closed unless processing is occurring. On July 12, 2013 white and (b) (4) residue was observed at the gasket on the (b) (4) valve on the (b) (4) side of the (b) (4) duct. The status of the equipment was "clean". When the (b) (4) valve was removed for further inspection white dust and white residue was observed inside of the (b) (4) duct work on the "HEPA filter" side of the (b) (4) valve. There is no procedure in place to inspect the "HEPA filter" side of the (b) (4) duct work and it had not previously been done. Approximately (b) (4) different products can be manufactured in this workshop.

2. Cleaning validation for the (b) (4) is deficient in that only (b) (4) samples are collected for analysis of product residues. No samples are taken from:

A. The (b) (4) side of the (b) (4) duct work or near the (b) (4) valve.
B. The main viewing window.
C. The parts that are removed and manually cleaned.

3. For cleaning validation of the (b) (4) there is no data to support the linearity and sample weights during analysis of the swab samples; for example: cleaning validation for (b) (4) tablets. (b) (4) and (b) (4)

OBSERVATION #4

A system for cleaning and disinfecting the aseptic filling room and equipment was not established to ensure aseptic conditions.

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1. Fumigation of the aseptic processing areas with (b) (4) is performed (b) (4) for control of spore forming organisms. During the validation of this process:

A. (b) (4) biological indicators were placed in the filling room. (b) (4) on the (b) (4) in the grade A area between the (b) (4) and (b) (4) on the (b) (4) in the grade B area. These locations do not demonstrate if the (b) (4) is able to permeate all areas inside of the filling barrier at a concentration effective to kill spores, including at the work surface.

B. No biological indicators were placed in the room with the vial (b) (4) where vials (b) (4) (b) (4)

C. There was no evaluation of the (b) (4) barrier surface (b) (4) or (b) (4) to determine whether residues of the (b) (4) remain after fumigation.

2. During the cleaning and disinfection of the (b) (4) filling room of line # (b) (4) on July 11, 2013 the following was observed:

A. The operators did not wipe all surfaces with disinfectant as described in procedure PO-5041H, "Cleaning and Line Clearance Procedure for Grade B Area". The operators sprayed disinfectant (b) (4) instead of using wipes.

B. During cleaning with (b) (4) all surfaces were not wiped as described in procedure PO-5041H. When operators returned to the filling room after changing the (b) (4) they did not always continue cleaning in the same location, causing some areas to be missed.

C. Wiping with (b) (4) did not always include working from the (b) (4)

D. An operator was observed to use a wipe on a surface in the grade B area and then use the same wipe for a surface in the grade A area. Procedure PO-5041H requires dedicated wipes for the grade A area.

E. The room is not designed to allow for sufficient cleaning of all areas. There is no (b) (4) for the barrier of the conveyor going to the capping room. This prevents the inside of the barriers for this area to be cleaned without the operator's gowns touching the already cleaned conveyor area.

3. Disinfectant efficacy studies have not been performed for all surfaces that are disinfected in the filling room, including, but not limited to: (b) (4) barrier surface (b) (4) and conveyor track (b) (4) (b) (4)

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OBSERVATION #5

For the process of performing a 100% visual inspection of finished vials:

1. Vials pass by (b) (4) visual inspectors on a conveyer belt at a speed of (b) (4) vials (b) (4) This speed does not allow for adequate inspection of all parts of the vial for defects or foreign matter.

2. The inspectors do not pick the vials up to move the (b) (4) Foreign matter can only be observed if it is present on the top of the filled (b) (4)

3. The vials are supposed to (b) (4) as they pass by the inspectors on the conveyor. However, it was observed that some vials only (b) (4) meaning not all sides of the vial could be inspected.

4. The operators do not pick up and inspect the vials to allow them to inspect for any defects on the bottom of the vials.

5. There is no assessment by QA to ensure the effectiveness of the visual inspection process during routine production.

6. For (b) (4) qualification of visual inspectors:

A. Defective vials used to qualify operators are chosen by a supervisor based on what defective vials are available from production at the time. There is no documentation to demonstrate that the chosen vials represent an adequate challenge to the operator. For example, all types of foreign matter that could be seen during production (glass, (b) (4) stopper particle, fiber, etc.) are not used to qualify the operator.

B. Operator fatigue is not considered. A qualification run can be completed in (b) (4) or less. Qualification is not performed at a time when the operators have been performing visual inspection for (b) (4) During routine production the inspectors will perform (b) (4) of inspection before a break.

OBSERVATION #6

Inadequate investigations were performed for laboratory and production deviations. Specifically,

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1. [redacted] (b) (4) Tablets, USP written investigation #201110203, lot # [redacted] (b) (4) was opened on 10/12/11 and closed on 10/25/11 for a dissolution failure. The investigation failed to document the observation of the dissolution analyst that explained the tablet was never dropped into the dissolution vessel.

2. [redacted] (b) (4) Injection, USP written investigation #201107204, lot # [redacted] (b) (4) was opened on 07/19/11 and closed on 07/20/11 failed to document all of the HPLC chromatograms. Only the retesting HPLC chromatograms were maintained. The original, failing, chromatograms were not maintained.

3. [redacted] (b) (4) Tablets, USP written investigation #201110201, lot # [redacted] (b) (4) opened on 10/08/11 and closed on 10/08/11 for a dissolution failure identified the incorrect vial positions in the HPLC tray as a root cause. However, the investigation failed to evaluate the actual vial positions in the HPLC tray to verify the root cause.

The preventive action of retraining analysts was not effective because [redacted] (b) (4) Injection, USP written investigation #201209201, lot # [redacted] (b) (4) was opened on 09/05/12 and closed on 09/10/12 for an OOS on assay and related substances. The root cause was identified as vials being placed in the wrong positions in the HPLC tray.

4. [redacted] (b) (4) Injection, USP written investigation #201205202, lot # [redacted] (b) (4) was opened on 05/29/12 and closed on 06/02/12 when a QC analyst noted that sample vials from the same batch had different versions of the label. No written investigation was performed nor documented to assess the impact of the wrong label not being detected by QC personnel during the incoming label sampling inspection or verification of labels during production. Additionally, the training records of the QC operators involved in the deviation were not reviewed. The firm does not have bar code scanning to control the labeling process.

5. Deviation EB-13003 (06/08/13), failed to determine a root cause for why QA failed to detect missing or erroneous information such as wrong weight numbers, batch record page not stamped with the control number, signature of the reviewer, batch size, and lot numbers during 2011 batch production records review. The batch records are [redacted] (b) (4) (b) (4)

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OBSERVATION #7

Procedures for laboratory methods are deficient:

1. The dissolution analysis of [(b) (4)] Tablets, USP [(b) (4)] is deficient in that it does not require the verification of the following at the time of use:

A. Distance between the bottom of the dissolution vessel and the paddle.
B. The temperature of the media in each vessel.
C. The number of revolutions per minutes (RPM).
D. The centering of the shaft/spindle.

2. There is no procedure in place for the degassing system used during the dissolution media preparation [(b) (4)] utilized in the dissolution test of [(b) (4)] Tablets, USP [(b) (4)]

3. HPLC vials are re-used for multiple analyses of different samples. The HPLC vial cleaning validation is deficient. The procedure does not cover all products produced that could be analyzed in the vials.

4. The weight variation test is performed by calculating the individual mass of [(b) (4)] vials and averaging the mass. The individual label amounts must be within [(b) (4)]% and the RSD not more than [(b) (4)]%. This weight variation calculation is not performed per USP <905>.

5. The assay for [(b) (4)] Injection is calculated using an average fill mass value from the weight variation. The sample used to perform assay is not taken from the composite generated after weighing the [(b) (4)] vials during weight variation determination.

OBSERVATION #8

Original data related to the production of the batch is not maintained and documented at the time of performance.

1. The intervention record and weight check portions of the batch production records are maintained inside of the aseptic fill rooms on laminated pages. Data is recorded on these erasable sheets. A copy of the laminated sheet is

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placed in the batch record. The original sheets are not maintained as a part of the batch record.

2. The (b) (4) captures continuous electronic data for monitoring the process, including (b) (4) and (b) (4). This electronic data is not saved or reviewed. An operator manually records values (b) (4) and only this manually recorded data is maintained and reviewed.

3. Data in the batch record is not recorded contemporaneously. Steps in the batch records are lumped together with one signature for multiple steps. An operator will sign for performing a step at the beginning of the step, before all parts are completed.

OBSERVATION #9

On July 8, 2013 a vial was dropped onto the floor during the labeling and packaging of batch (b) (4) (b) (4) injection. This was after visual inspection of the vials. The vial was picked up and placed back on the production line. There was no inspection to evaluate whether dropping the vial on the floor compromised the integrity of the vial.

OBSERVATION #10

Calibration of the following laboratory equipment was found deficient:

1. During calibration of HPLCs, the sample energy and reference energy is not performed
2. SOP #MM-0026C 'Calibration for Electronic Balances' effective 01/01/11 does not document the weight mass used during calibration. Additionally, the minimum weight test is not performed.
3. There is no test procedure for the Karl Fisher instrument (b) (4) qualification.
4. There is no test procedure for the Polarimeter instrument (b) (4) qualification.

OBSERVATION #11

Extractable and leachable studies for the (b) (4) stoppers used to manufacture the (b) (4) injection products have not been completed.

OBSERVATION #12

The QC laboratory does not have the (b) (4) detector need to test the Limit of (b) (4)

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(b) (4) [redacted] in (b) (4) [redacted] injection, USP (b) (4) [redacted]

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