DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857 email: orapharminternationalresponses@fda.hhs.gov	6/12-16/2023
	FEI NUMBER 3021324493

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Zhang Hanchang, Vice President and General Manager

FIRM NAME	STREET ADDRESS
Qilu Pharmaceutical Co., Ltd.	No. 849 Dongjia Town, Licheng District
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Jinan, Shandong 250105, China	Sterile API Manufacturer

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

1) There is no non-viable air sampling or active viable air sampling during production in the restricted access barrier system used to aseptically fill and seal canisters of (b) (4) (b) (4) sterile drug substance on line (b) (4)

2) The (b) (4) attached to the restricted access barrier system used to aseptically produce sterile drug substance on line (b) (4) are disinfected up to (b) (4) before use in aseptic production and are not disinfected again before use or before (b) (4) interventions.

3) The sterilized reusable microfiber cleaning cloths used to clean and disinfect the interior of the restricted access barrier system used to aseptically fill and seal canisters of (b) (4) sterile drug substance on line (b) (4) have been shown to shed visible particulates during qualification study V-C-(R)-660102700008 and are stored in open (b) (4) bowls in the Grade B environment before being brought into the unit for cleaning.

4) The Grade B area containing the restricted access barrier system used to aseptically fill and seal canisters of (b) (4) sterile drug substance on line (b) (4) has a long, looped power cord and (b) (4) stand and (b) (4) shelving with extra equipment not used in the current filling operation stored in the area just outside the restricted access barrier system.

5) Airflow visualization studies used to qualify the operation of the restricted access barrier system used to aseptically fill and seal canisters of (b) (4) sterile drug substance on line (b) (4) do not allow adequate visualization of the airflow patterns at critical areas at the filling and capping stations.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Matthew Casale	**Matthew B. Casale, Investigator**	**06/16/2023**

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

6) Four out of four deviation and out-of-specification investigations reviewed did not include root causes and actions to be taken to prevent a reoccurrence that were fully justified by the investigation. For example:

a. Deviation C0719007 was an investigation opened due to a data recording system was not operating while a production system was, causing a loss of data. The root cause was identified as an error due to use of a previous software version. The correction was to update the software system. The investigation does not discuss why the software had not been updated prior to this issue and what action could be taken to prevent a reoccurrence of the issue.

b. Deviation C0719007 was an investigation opened due to the (b) (4) water system passing the disinfection timeframe without being sanitized. The root cause was identified as a lack of reminder in the logbook or a label saying the system needed to be sanitized next. The correction was to add a reminder to the logbook and a reminder sticker. The investigation does not ask why the water system didn't have these items to begin with or what action could be taken to prevent a reoccurrence of the issue.

c. Out-of-specification investigation 202012-D63-04 was opened due to the presence of two unknown peaks in a stability sample of (b) (4) sterile API. The root cause was attributed to an employee missing a glassware washing step. The investigation was later reopened, and the root cause was attributed to inadequate instructions for the washing step. The investigation does not address why the washing step was not adequately described in the first place, the washing step is still not documented in the preparation record, and there is no discussion of what actions could be taken to prevent a reoccurrence of these issues.

d. Out-of-expected investigation 202304-D63-01 was opened due to a decreasing impurity trend identified on stability for (b) (4) sterile API. One root cause was attributed to a difference in testing results when using HPLCs from different manufacturers. The correction was to only use the system from one manufacturer to perform related substances testing on (b) (4) sterile API. The investigation does not discuss why the systems from both manufacturers were not evaluated in the method validation or what action could be taken to prevent a reoccurrence of the issue.