DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
United States Food and Drug Administration 12420 Parklawn Dr., Room 2032 Rockville, MD 20857 ORAPHARMInternational483responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	04/20-23/2022, 04/26-28/2022
	FEI NUMBER 3009831352

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Wang Yongjin, General Manager

FIRM NAME	STREET ADDRESS
QILU ANTIBIOTICS PHARMACEUTICAL CO. LTD	No. 849 Dongjia Town
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Licheng District Jinan, Shandong CN 250105	Drug 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

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room, equipment to produce aseptic conditions.

Specifically,

A) Fumigation of (b) (4) n Units (b) (4) occur (b) (4) changes for (b) (4) and (b) (4) in Units (b) (4) I reviewed the following documents related to the validation study for fumigation.

- "Validation Report for Premises Fumigation", SV-FUST (b) (4) 01, Approval Date: 06/22/2020 (Unit (b) (4)
- "Validation Report for Premises Fumigation", SV-FUST 01, Approval Date: 10/13/2020 (Unit
- "Validation Report for Premises Fumigation", SV-FUST 01, Approval Date: 07/27/2020 (Unit

The validation reports are inadequate as they do not fully assess the scientific rationale for the placement of biological indicators at hard to reach areas. For example, there are (b) RABS (b) (4) located in Unit (b) (4) (b) (4) RABS (b) (4) located in Unit (b) (4) and (b) (4) RABS (b) (4) located in Unit (b) (4) During the validation no RABS (b) (4) were challenged with the biological indicators.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Marcus A. Ray, Investigator	04/28/2021

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
United States Food and Drug Administration 12420 Parklawn Dr., Room 2032 Rockville, MD 20857 ORAPHARMInternational483responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	04/20-23/2022, 04/26-28/2022
	FEI NUMBER 3009831352

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Wang Yongjin, General Manager

FIRM NAME	STREET ADDRESS
QILU ANTIBIOTICS PHARMACEUTICAL CO. LTD	No. 849 Dongjia Town
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Licheng District Jinan, Shandong CN 250105	Drug Manufacturer

B) On 04/23/2021, I reviewed the closed caption tv (CCTV) system for (b) (4) Unit (b) (4) for the manufacturing of the sterile API (b) (4) Batch No: (b) (4) I observed an Operator (b) (4) (b) (4) of the RABS and place the (b) (4) the RABS: however, the arm of the Operator extended into the Grade A area of the RABS. The Workshop Manager of (b) (4) confirmed there is no approved procedure to provide cleaning instructions, such as wiping the (b) (4) of the Grade A area with a disinfectant after Operators enter.

OBSERVATION 2

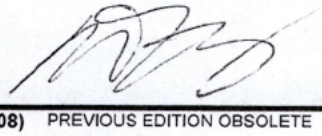
Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not followed.

Specifically,

SOP PLA1160, "Operating Procedures for Visual Inspection of (b) (4) ", defines the different types of defects (critical, major, minor) and identifies that Operators will perform a 100% check on filled vials and reject vials that meet the criteria of critical, major, and/or minor defects.

During the review of the retain/reserve samples located in (b) (4) I observed multiple vials with defects, that were not rejected during the 100% visual inspection. Approximately, (b) (4) for each product and batch number identified, containing (b) (4) vials each were randomly selected during my review.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
		Marcus A. Ray, Investigator	04/28/2021

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
United States Food and Drug Administration 12420 Parklawn Dr., Room 2032 Rockville, MD 20857 ORAPHARMInternational483responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	04/20-23/2022, 04/26-28/2022
	FEI NUMBER 3009831352

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Wang Yongjin, General Manager

FIRM NAME	STREET ADDRESS
QILU ANTIBIOTICS PHARMACEUTICAL CO. LTD	No. 849 Dongjia Town
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Licheng District Jinan, Shandong CN 250105	Drug Manufacturer

For example,

Product	Batch Number	Manufacturing Date	Defect	Category	Number of Defect Vials
(b) (4) [redacted]					

OBSERVATION 3

The persons double-checking the cleaning and maintenance are not dating, signing, or initialing the equipment cleaning and use log.

Specifically,

I reviewed the equipment log books and observed a two (2) person verification for activities performed is not documented in the equipment log books.

For example, the following log books did not have a two (2) person verification of activities performed:

(b) (4) [redacted] Equipment ID: FD36102
- RABS Filling, Equipment ID: RABS36101
- Filling Machine, Equipment ID: SF36301
- Filling Machine, Equipment ID: SF36401

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Marcus A. Ray, Investigator	04/28/2021