

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Use this check box to generate the required 483 statement on page 1 for medical device observations.

DISTRICT OFFICE ADDRESS AND PHONE NUMBER

CDER/OC/OMPQ/ICT HFD-325
10903 New Hampshire Ave, Bldg 51, Rm 4225
Silver Spring, MD 20993 USA
CDERICT@FDA.HHS.GOV

DATE(S) OF INSPECTION

9/8/13, 14, 15, 18, 19, 20/2017
NBR 9/24/17

FEI NUMBER

3003802432

Industry Information: www.fda.gov/oc/industry

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Bao Haizhang, General manager of Factory

FIRM NAME

Qilu Pharmaceutical Co. Ltd.

STREET ADDRESS

317 Xinluo Road High Tech Zone

CITY, STATE AND ZIP CODE

Jinan, Shandong China 250101

TYPE OF ESTABLISHMENT INSPECTED

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:

Laboratory

Observation 1

Personnel monitoring after performing aseptic operations is deficient.

Specifically,

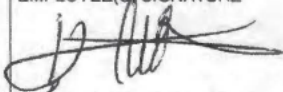
Procedure PO-B080081 does not describe in enough detail the procedure for taking operator finger samples after aseptic operations. For example, the SOP description of sampling is,

"... touch the surface of media with five fingers together for at least (b)(4). Press evenly and carefully not to damage the media surface. Once contact, fingers cannot move on the media surface..." According to management the operators press, but do not (b)(4) fingers when collecting samples.

Add Continuation Page

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE



EMPLOYEE(S) NAME AND TITLE (Print or Type)

Marjio B. Kambeve, CSO

DATE ISSUED

9/8/20/17
NBR 9/24/17

Lindsay M. Schumacher

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."