

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER

United States Food and Drug Administration  
12420 Parklawn Drive, Rm 2032, Rockville, MD 20857  
DRAPHARM International 483 responses @ fda-hhs.gov

DATE(S) OF INSPECTION

02/27/2023 - 03/03/2023

FEI NUMBER

3014784835

Industry Information: [www.fda.gov/oc/industry](http://www.fda.gov/oc/industry)

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Dirk Tormans, VP, Head of STA, QA

FIRM NAME

WUXI STA Pharmaceutical Co., LTD.

STREET ADDRESS

No 8 Xinrui Road, Xinwu District

CITY, STATE AND ZIP CODE

WUXI, CN, 214028

TYPE OF ESTABLISHMENT INSPECTED

Contract Manufacturing Organization

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

Routine calibrations of mechanical measuring instruments are not performed according to written procedures.

Specifically,

Your firm completed a Balance Calibration Plan for (b) (4) which states that calibration should be performed (b) (4) However, your firm did not perform (b) (4) calibrations for the following mechanical instruments.

- (b) (4) Sensor (ID: 2-(b) (4) RTP-01)
- (b) (4) Sensor (ID: 2-(b) (4) RTP-01)
- Balance (ID: 2-PR-B-20)
- Balance (ID: 2-PR-B-21)

In addition, these mechanical instruments are used in the manufacturing process for (b) (4) (b) (4) (b) (4)

SEE  
REVERSE  
OF THIS  
PAGE

EMPLOYEE(S) SIGNATURE

Tonia Bernard

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

Tonia Bernard, Investigator

DATE ISSUED

03/03/2023