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 ORAPHARMIntemationalresponses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	11/04/2024-11/08/2024
	FEI NUMBER 3005310494

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Li Yang, General Manager

FIRM NAME	STREET ADDRESS
Lights Medical Manufacture Co., Ltd	No. 19 Quanda Road, Wuqing Development Area
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Tianjin, Tianjin, 301700, China	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

Procedures applicable to the quality unit are not fully followed

Specifically,

The firm's SOP LIG/PCD-ZL-09-E/4 "Change Control Procedure", effective date: 10/16/2024, requires change control to be completed for all equipment used directly in production and quality control testing that impacts product quality. However, your firm did not have a change control documentation for the Potentiometric Titrator (ID: HY-121) and pH Meter (ID: HY-120), which are used to test the assay and pH of finished over-the-counter drug (OTC) drug products, including (b) (4) (b) (4)

OBSERVATION 2

Written records of major equipment use are not included in individual equipment logs.

Specifically,

Your firm does not maintain equipment use logs for equipment used in the manufacturing process of over-the-counter drug products. This includes, but is not limited to, the following equipment:

Name of Manufacturing Equipment Equipment ID(s)

(b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Tonia Bernard, CSO	Tonia Bernard, Investigator	11/08/2024

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APPEARS THIS WAY
ON THE ORIGINAL

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	Tonia Bernard, CSO	Tonia Bernard, Investigator	11/08/2024