

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

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| DISTRICT OFFICE ADDRESS AND PHONE NUMBER<br><br>United States Food and Drug Administration<br>12420 Parklawn Dr., Room 2032 Rockville, MD 20857<br>ORAPHARMInternationalresponses@fda.hhs.gov<br><br>Industry Information: www.fda.gov/oc/industry | DATE(S) OF INSPECTION<br>11/04/2024-11/08/2024 |
|                                                                                                                                                                                                                                                    | FEI NUMBER<br>3005310494                       |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED  
**TO: Mr. Li Yang, General Manager**

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

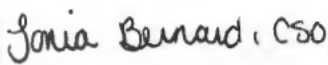
Written records of major equipment use are not included in individual equipment logs.

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<br>REVERSE<br>OF THIS<br>PAGE | EMPLOYEE(S) SIGNATURE<br> | EMPLOYEE(S) NAME AND TITLE (Print or Type)<br>Tonia Bernard, Investigator | DATE ISSUED<br>11/08/2024 |
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| NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED<br>TO: Mr. Li Yang, General Manager                                                                                                                                                  |                                                               | FEI NUMBER<br>3005310494                                                  |                           |
| FIRM NAME<br>Lights Medical Manufacture Co., Ltd                                                                                                                                                                                           | STREET ADDRESS<br>No. 19 Quanda Road, Wuqing Development Area |                                                                           |                           |
| CITY, STATE AND ZIP CODE<br>Tianjin, Tianjin, 301700, China                                                                                                                                                                                | TYPE OF ESTABLISHMENT INSPECTED<br>Drug Manufacturer          |                                                                           |                           |
| <div>APPEARS THIS WAY<br/>ON THE ORIGINAL</div>                                                                                                                                                                                            |                                                               |                                                                           |                           |
| SEE<br>REVERSE<br>OF THIS<br>PAGE                                                                                                                                                                                                          | EMPLOYEE(S) SIGNATURE<br><i>Tonia Bernard, CSO</i>            | EMPLOYEE(S) NAME AND TITLE (Print or Type)<br>Tonia Bernard, Investigator | DATE ISSUED<br>11/08/2024 |