

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

| | |
|---|--|
| DISTRICT ADDRESS AND PHONE NUMBER 60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax: (404)253-1202 | DATE(S) OF INSPECTION 4/16/2018-4/20/2018 |
| | FEI NUMBER 3011158388 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Lou Kennedy, Chief Executive Officer:

| | |
|--|--|
| FIRM NAME Nephron Pharmaceuticals Corporation dba Nephron Sterile Compounding Center | STREET ADDRESS 4500 12th Street Ext |
|--|--|

| | |
|--|--|
| CITY, STATE, ZIP CODE, COUNTRY West Columbia, SC 29172-3025 | TYPE ESTABLISHMENT INSPECTED Compounding Facility |
|--|--|

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 WE OBSERVED:
OBSERVATION 1**

Clothing of personnel engaged in the manufacturing of drug products is not appropriate for the duties they perform.

Specifically, on 04/16/2018 we observed a sterile pharmacy technician in the ISO 7 area with their neck skin clearly visible due to improper gowning. The technician went into the ISO 8 area to fix the gowning, and returned to the ISO 7 after spraying gloved hands with (b) (4) but without replacing gloves. Additionally, the safety goggles used by all sterile technicians and the supervising pharmacist in the ISO 7 compounding areas, and working in the ISO 5 laminar flow hoods, have (b) (4) (b) (4) that may allow contamination of the aseptic compounding area.

| | | | |
|---------------------------------|---|---|--------------------------|
| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE Seneca D Toms, Investigator Larry K Hampton, Investigator | Larry K Hampton Investigator Signed By Larry K Hampton -S Date Signed 04-20-2018 13:59:53 X | DATE ISSUED 4/20/2018 |
| | | | |

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

| | |
|---|--|
| DISTRICT ADDRESS AND PHONE NUMBER 60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax: (404)253-1202 | DATE(S) OF INSPECTION 4/16/2018-4/20/2018 |
| | FEI NUMBER 3011158388 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Lou Kennedy, Chief Executive Officer:

| | |
|--|--|
| FIRM NAME Nephron Pharmaceuticals Corporation dba Nephron Sterile Compounding Center | STREET ADDRESS 4500 12th Street Ext |
| CITY, STATE, ZIP CODE, COUNTRY West Columbia, SC 29172-3025 | TYPE ESTABLISHMENT INSPECTED Compounding Facility |

X Seneca D Toms
Investigator
Signed By: 2000562667
Date Signed: 04-20-2018 14:01:28

| | | | |
|-------------------------------------|---|--|--------------------------|
| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE Seneca D Toms, Investigator Larry K Hampton, Investigator | Larry K Hampton Investigator Signed By: Larry K Hampton-S Date Signed: 04-20-2018 13:59:53 X _____ | DATE ISSUED 4/20/2018 |
| | | | |