

**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 10/28/2019-11/15/2019* FEI NUMBER 3011158388
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
Lou Kennedy, CEO

FIRM NAME Nephron Pharmaceuticals Corporation dba Nephron Sterile Compounding Center	STREET ADDRESS 4500 12th Street Ext
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CITY, STATE, ZIP CODE, COUNTRY West Columbia, SC 29172-3025	TYPE ESTABLISHMENT INSPECTED 503B Outsourcing Facility
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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**

Test procedures relative to appropriate laboratory testing for sterility are not written and followed. Specifically, the firm's written procedures for conducting (b) (4) rapid sterility testing are deficient in that:

1. Finished drug product (b) (4) rapid sterility test samples deemed by firm personnel to be "background too high", verbally defined as samples displaying more than (b) (4) events, are not fully examined. The firm discards the sample results and the product lot is (b) (4). If this (b) (4) "background too high", the firm will (b) (4). No investigations are conducted for test deemed as "background too high". Samples have been deemed "background too high" approximately 23 times in the last 90 days.

Additionally, during the execution of rapid sterility sample preparation on November 4, a laboratory analyst was observed practicing poor aseptic technique including passing their hands over open containers and exposed samples on at least three occasions, which could lead to the introduction of microbial and particulate contamination of the samples.

2. There is no written definition of "background too high" in the firm's procedure, which was verbally described as samples with more than (b) (4) events.
3. There are no instructions for the firm's practice of discarding samples deemed to have "background too high" and then (b) (4)

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Jessica L Pressley, Investigator Jared P Stevens, Investigator Seneca D Toms, Investigator	DATE ISSUED 11/15/2019
		

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4. The firm does not have procedures requiring eye exams for individuals that conduct review of rapid sterility test sample results (b) (4) examination.
  
5. Procedures do not require observance of actual positive microbial events by an analyst prior to performance of sterility testing conducted for commercial products. During the inspection it was observed that an individual was allowed to conduct inspection of (b) (4) rapid sterility samples, including (b) (4) prior to the completion of activities to demonstrate they have seen and can identify what a positive microbial event looks like (b) (4). For example, during the period from October 3, 2019 to October 29, 2019, a laboratory associate was allowed to conduct finished product rapid sterility testing prior to the associate participating in a method validation on October 29, 2019, where according to firm management they would have seen an identified positive microbial event example for the first time at the firm. During this time, the associate conducted test for multiple lots of product, including but not limited to rapid sterility sample ID sets (b) (4), (b) (4), (b) (4) and (b) (4).

**OBSERVATION 2**

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not followed,

Specifically,

- 1-6. ~~5B~~ Your firm failed to follow SOP.CM.4102, Version 6 (dated: 6/3/19) entitled, "Aseptic Processing and Technique", Section: 6.3.2 Principles of Aseptic Technique as evidenced by the following examples:
  - a. According to your (b) (4) on 10/26/19, at approximately (b) (4) during the filling of Succinylcholine Chloride Injection, USP 200mg/10mL (preservative free), lot # SU9083A, the aseptic technique of your firm's operator was not adequate as they were observed opening the Luer Lock IV Syringe Cap

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Jessica L Pressley, Investigator Jared P Stevens, Investigator Seneca D Toms, Investigator		DATE ISSUED 11/15/2019

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containers directly over the firm's (b) (4) cap scoop containing caps (product contact surface), blocking first air, then was observed opening the door to the (b) (4) (b) (4) filling line and touching the feeder containing the Luer Lock IV Syringe Caps with their gloved hand. In addition, from approximately (b) (4) (b) (4) your firm's operators were observed sanitizing their gloved hands prior to personnel monitoring of their sleeves and gloved hands (conducted at approximately (b) (4))

b. According to your (b) (4), on 10/26/19, at approximately (b) (4) during the filling of Succinylcholine Chloride Injection, USP 200mg/10mL (preservative free), lot # SU9083A an operator was observed moving rapidly within the ISO-5 Clean Room carrying a tote containing Luer Lock IV Syringe Cap containers. The tote and the gloved hands of the operator came in direct contact with the sterile caps that were exposed within the (b) (4) cap scoop. The same operator was observed tossing the Luer Lock IV Syringe Cap containers from one tote to another within the cap loading area.

27. Your firm failed to follow SOP.CM.4928, Version 10 (dated: 9/9/19) entitled, "Manual Syringe Filling Operations Procedure", Section: 6.6 Filling Syringes and Section: 6.7 Capping Syringes as evidenced by the following example: on 10/29/19, two technicians were not exhibiting slow and controlled movements within the ISO-5 Hood during the filling and stoppering of Neostigmine Methylsulfate for injection, USP 3mg/3mL (1mg/mL) preservative free, lot # NE9066 within filling room, (b) (4)

38. Your firm's smoke studies are inadequate as they do not demonstrate that your hood and/or line is designed to prevent microbiological contamination, or to provide high assurance of product sterility as evidenced by the following examples:

a. On 7/25/19, within the firm's ISO 5 Clean Room, #(b) (4) containing the firm's (b) (4) filling line, laminar air flow was not demonstrated as turbulent air flow was

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Jessica L Pressley, Investigator Jared P Stevens, Investigator Seneca D Toms, Investigator	 x	DATE ISSUED 11/15/2019

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observed within the smoke study videos entitled, "July 25, 2019 Bowl.MP4", "July 25, 2019 Feeder.MP4" and July 25, 2019 Filler.MP4".

- b. On 4/25/19, within the firm's ISO 5 Hood # (b) (4) located in Clean Room (b) (4), first air from the (b) (4) HEPA filter was being blocked by the equipment (repeater pump) within the hood and the video failed to demonstrate laminar airflow around the equipment when open syringes are connected to the filling tubing. In addition, your firm fails to capture the loading and un-loading of components by the additional operators within the ISO 5 Hood (during operations there is a potential for (b) (4) operators to be present working within the ISO 5 Hood).

**OBSERVATION 3**

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

1. Your firm failed to follow SOP.MB.4501, Version 17 (dated: 8/19/19) entitled, "Environmental and Personnel Monitoring", Section: 6.3.5 Personnel Sampling as evidenced by the following example: on 10/30/19, during personnel monitoring, technicians were observed quickly tapping their fingertips to each media plate, rather than rolling their fingers to capture the gloved hands utilized during aseptic production. In addition, one technician was observed with wet gloves from previously spraying them with (b) (4) prior to sampling which is inadequate and not considered representative of aseptic production.
2. Your firm's SOP.MB.4501, Version 17 (dated: 8/19/19) entitled, "Environmental and Personnel Monitoring", Attachment 20-Sampling for (b) (4)s inadequate as evidenced by the following

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example: surface samples are not conducted for the (b) (4) cap scooper at the completion of the (b) (4) filling process (b) (4). The (b) (4) cap scooper is utilized to dispense the sterile Luer Lock IV Syringe caps (product contact surface) into the cap hopper inside the (b) (4) filling line.

**OBSERVATION 4**

Written procedures for sampling and testing plans are not followed for each drug product.

Specifically, your firm failed to follow SOP.QC.4301, Version 19 (dated: 8/20/19), Section: 6.5 100% Syringe Visual Inspection as evidenced by the following example: on 10/29/19, your firm's technician was observed exhibiting poor technique while quickly and incompletely inverting the sterile syringes (clear plastic) during the visual inspection process for Phenylephrine HCL Injection, 10 mL lot #PE9194A.

**OBSERVATION 5**

Aseptic processing areas are deficient in that floors and walls are not smooth and/or hard surfaces that are easily cleanable.

Specifically, your firm's ISO-7 Clean rooms (b) (4) where aseptic processing is performed contain floor drains which appear un-clean and stained. Additionally, on 10/30/19, blue painter's tape was observed affixed to the corner of your firm's clean room wall (b) (4) and glass frame covering the gap between areas. The floor drains and blue painter's tape cannot be easily cleaned or sanitized.

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Jessica L Pressley, Investigator Jared P Stevens, Investigator Seneca D Toms, Investigator	 _____ x	DATE ISSUED 11/15/2019

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**OBSERVATION 6**

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically, your firm failed to follow SOP.SR.2501, Version 18.0, Cleaning of Classified Environments for Nephron 503b Outsourcing Facility (dated: 8/15/2019), Section 6 – Procedure, as evidenced by the following example: on 10/28/19, during the formulation of Neostigmine, 1mg/mL (3mL) lot #NE9066 it was observed that within Compounding Suite (b) (4), Room (b) (4) (ISO-7), the base of the loading ramp leading onto the floor production scale contains a black-colored substance and is stained. The cleaning log for that suite, (b) (4) Floor Cleanroom Cleaning/Sanitization Log, (PR: 1002134), effective 8/28/2019, shows startup cleaning prior to formulation, on 10-28-2019, however the observed growth within the classified area does not support that cleaning within the suite was adequate.

**OBSERVATION 7**

Established test procedures are not documented at the time of performance.

Specifically, The firm does not maintain documentation of the start, stop or elapsed time for the incubation of rapid sterility test (b) (4). The firm only temporarily records start and due/end times on a piece of tape on the box holding the sample (b) (4). This tape is discarded following testing. Incubation within established time and temperature specification is important in obtaining valid product sterility results.

**OBSERVATION 8**

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Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically,

1. The computer systems used to locally store sterility sample results for the firm's (b) (4) instruments allows the addition and deletion of files in the directory used for storage of (b) (4) data while logged in under the Windows operating system's shared general laboratory user login.
2. According to the firm's Chief Technology Officer (b) (4) sterility testing data is supposed to be backed up (b) (4); however, data file backup did not occur for one of the firm's (b) (4) computer systems from August of 2019 to November 4, 2019. During the time since the backup stopped, approximately (b) (4) samples runs were conducted on the instrument.
3. The (b) (4) system allows for the deletion of the audit trail on the computers. The audit trail prior to August 2019 for one of the (b) (4) computers was deleted from one of (b) (4) computer systems. The system has been in used since (b) (4).

**OBSERVATION 9**

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically, the firm does not conduct investigations when finished product rapid sterility samples are deemed "background too high". Samples were deemed "background too high" approximately 23 times in the last 90 days, with no investigations performed. The source nor cause of the high event counts have been identified. The product is (b) (4) (b) (4) (b) (4) without identification of the cause, nor examination to identify

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the events. In all cases with the exception of a recent "background too high" sample which is currently undergoing (b) (4) sterility testing on the (b) (4) sampling of the lot, products have been released as passing sterility based on (b) (4) or (b) (4) sampling passing.

**\*DATES OF INSPECTION**

10/28/2019(Mon), 10/29/2019(Tue), 10/30/2019(Wed), 10/31/2019(Thu), 11/01/2019(Fri),  
11/04/2019(Mon), 11/05/2019(Tue), 11/06/2019(Wed), 11/07/2019(Thu), 11/15/2019(Fri)

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Jessica L Pressley, Investigator Jared P Stevens, Investigator Seneca D Toms, Investigator		DATE ISSUED 11/15/2019