DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	8/11/2025-8/22/2025* FEI NUMBER 3010892830

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Lou Kennedy , CEO

FIRM NAME	STREET ADDRESS
Nephron Sc Inc	4500 12th Street Ext
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
West Columbia, SC 29172-3025	Sterile Drug Manufacturing & 503B Outsourcing 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

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and written.

503B Outsourcing Facility

Specifically,

A. Your firm failed to perform adequate airflow-visualization (smoke) studies under dynamic conditions representative of actual aseptic operations. Specifically, for example, but not limited to, the following:

   a. Laminar Flow Hood (LFH) Equipment: Smoke studies for the LFH was not conducted under dynamic conditions representative of actual operations. The studies did not demonstrate unidirectional airflow protection of all critical zones during interventions, including set-up and material manipulations.

   b. (b) (4) Syringe Filler (Room (b) (4), Equipment ID/NID # (b) (4) : Airflow visualization (smoke studies) for the (b) (4) syringe filler were not performed under dynamic conditions representative of actual aseptic operations, including interventions and operator activities. The current approved study did not demonstrate that unidirectional airflow is maintained over all critical zones to protect exposed sterile product from contamination.

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Saundrea A Munroe, Investigator Rose L Jean-Mary, Investigator Kellia N Hicks, Investigator Simone E Pitts, National Expert X Saundrea A Munroe Investigator Signed By: Saundrea A. Munroe - S Date Signed: 08-22-2025 20:21:05	8/22/2025

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	8/11/2025-8/22/2025* FEI NUMBER 3010892830

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Lou Kennedy , CEO	
FIRM NAME Nephron Sc Inc	STREET ADDRESS 4500 12th Street Ext
CITY, STATE, ZIP CODE, COUNTRY West Columbia, SC 29172-3025	TYPE ESTABLISHMENT INSPECTED Sterile Drug Manufacturing & 503B Outsourcing Facility

c. Cleanroom Design / LFH Placement: The main cleanroom door is directly in line with the LFH. During filling operations, this door was observed to be opened multiple times, creating the potential for airflow disruption and loss of ISO 5 protection in the LFH critical zone. This scenario was not simulated in your smoke studies and has not been evaluated under actual operational conditions.

Your firm failed to demonstrate through scientifically sound smoke studies that unidirectional airflow and first air are consistently maintained in ISO 5 classified areas during actual aseptic processing an including activity in the background environment which can disrupt airflow. Without adequate airflow visualization, sterile products may be produced in an environment that does not provide sufficient protection against microbiological contamination.

B. Your firm failed to adequately control aseptic operations, enforce proper personnel practices, and implement effective contamination controls. These deficiencies in aseptic practices create an unacceptable risk of microbial contamination to sterile drug products administered directly to patients' cardiovascular systems. For example, but not limited to, during the aseptic filling of Batch #NC-5128A of 1000 ml Del Nido Cardioplegia Solution in Laminar Flow Hood (LFH)-(b) (4), Room (b) (4), and Batch #NC-5128B in LFH-(b) (4), Room (b) (4) we observed the following poor aseptic practices:

1. Your firm failed to sanitize IV bags prior to their introduction into the ISO 5 laminar flow hoods; operators transferred overwrapped IV bags from the ISO 7 area and placed them directly on critical surfaces without wiping with new sterile (b) (4) wipes.
2. Your firm failed to ensure operators performed slow and deliberate movements in the ISO 5 critical area; operators were observed moving rapidly in a manner that disrupted unidirectional airflow.

AMENDMENT 1

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	8/11/2025-8/22/2025* FEI NUMBER 3010892830

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Lou Kennedy , CEO	
FIRM NAME Nephron Sc Inc	STREET ADDRESS 4500 12th Street Ext
CITY, STATE, ZIP CODE, COUNTRY West Columbia, SC 29172-3025	TYPE ESTABLISHMENT INSPECTED Sterile Drug Manufacturing & 503B Outsourcing Facility

3. Your firm failed to require operators to sanitize their hands prior to transferring materials into the ISO 5 area.
4. Your firm failed to control the cleanroom environment; trash removal was conducted while filling operations were in progress without halting production.
5. Your firm failed to prevent unnecessary particulate generation; operators moved shelving containing tubs of filled and bulk IV bags during active filling.
6. Your firm failed to maintain segregation and control of critical areas; the main doors to manufacturing rooms were opened during aseptic operations, and in Room (b) (4) the door was directly in line with the critical surface of the LFH.
7. Your firm failed to enforce proper gowning practices; operators were observed removing and replacing sleeves and gloves in the background area during filling operations.
8. Your firm failed to ensure disinfectants and sanitizing materials were used appropriately; (b) (4) wipes intended for single use were reused multiple times after being left exposed on shelving.
9. Your firm failed to ensure the integrity of personnel monitoring data; a microbiologist was observed spraying his hands with disinfectant immediately prior to performing his own personnel monitoring, thereby biasing results.

These repeated and systemic lapses demonstrate that your firm has not implemented or enforced adequate aseptic practices to maintain sterility assurance of drug products.

Sterile Drug Manufacturing & 503B Outsourcing Facility

C. Your firm's media fill program does not ensure simulations are representative of routine

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Saundrea A Munroe, Investigator Rose L Jean-Mary, Investigator Kellia N Hicks, Investigator Simone E Pitts, National Expert X Saundrea A Munroe Investigator Signed By: Saundrea A. Munroe - S Date Signed: 08-22-2025 20:21:05	8/22/2025

commercial operations or worst-case conditions.

1. Media fill protocols and executed records simulate critical interventions only "at least (b) (4)" rather than at a representative number, type, complexity, and frequency justified by actual production history. This reduces the intervention load and fails to reflect worst-case conditions.

2. Routine production batch records do not consistently document the type, frequency, and timing of interventions, including non-routine/unplanned interventions, preventing data-driven justification of media fill design.

As designed and executed, the media fills do not provide adequate assurance of sterility for commercial operations, increasing the risk of undetected contamination during routine aseptic processing.

D. You have not demonstrated in your disinfectant efficacy study that your established contact time of (b) (4) for sterile (b) (4) used as a disinfectant in your facility is capable of decontaminating (b) (4) surfaces. (b) (4) gloves are primarily used for operating within the ISO-5 and ISO-7 cleanroom environments where sterile drug products are manufactured.

This is a repeated observation from the inspection performed 11/2023 – 02/2023, 01/29/2024 – 02/09/2024.

OBSERVATION 2

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

AMENDMENT 1

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	8/11/2025-8/22/2025* FEI NUMBER 3010892830

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Lou Kennedy , CEO

FIRM NAME	STREET ADDRESS
Nephron Sc Inc	4500 12th Street Ext
CITY, STATE, ZIP CODE, COUNTRY West Columbia, SC 29172-3025	TYPE ESTABLISHMENT INSPECTED Sterile Drug Manufacturing & 503B Outsourcing Facility

503B Outsourcing Facility

Specifically,

A. Your firm failed to establish and implement an adequate environmental monitoring (EM) program that includes all critical surfaces and locations within classified areas.

For example, but not limited to, your firm's EM program does not include sampling of the operator contact portion of the barrier on the (b) (4) Automated Syringe Filler in Room (b) (4) Syringe Filler (Equipment ID/NID # (b) (4) Cap Barrier and Syringe Barrier during aseptic operations. These surfaces are also excluded from your firm's cleaning and disinfection program, despite its direct contact with operators and proximity to the ISO 5 critical zone.

Your firm failed to ensure that all high-risk and frequently touched surfaces in classified areas are routinely monitored and disinfected to detect and prevent microbial contamination. These deficiencies in the environmental monitoring and cleaning program create an unacceptable risk of undetected microbial contamination of sterile drug products administered directly to patients' cardiovascular systems. The lack of effective contamination control undermines sterility assurance and patient safety.

B. Your firms' personnel monitoring program does not include all areas of the gown or body that may contact critical surfaces during operations. For example, the operator's forearm, identified by your firm as a frequent recovery site, is not routinely sampled when loading caps on the (b) (4) Automated Syringe Filler (Equipment ID/NID #(b) (4)) in Room (b) (4) Syringe Filler). Your firm failed to establish and follow an adequate personnel monitoring program designed to detect contamination on high-risk operator surfaces in proximity to aseptic operations. For example, during review of smoke study footage for the (b) (4)

AMENDMENT 1

Automated Syringe Filler (Equipment ID/NID #(b) (4)) in Room (b) (4) Syringe Filler), at time point 43:03-43:04, we observed the top of the operator's forearm contacting the underside of the operator contact barrier, which separates the operator from the ISO 5 critical zone. This location is not included in your firm's routine personnel monitoring program.

Your firm's management acknowledged that the forearm is a common site for recovery of objectionable microorganisms. Despite this, your personnel monitoring program does not include routine sampling of this point on the forearms, and the contact surface itself is excluded from your environmental monitoring and cleaning programs.

Your firm failed to implement an adequate personnel monitoring program to identify and control microbial risks associated with operator interactions at the barrier system. These deficiencies create an unacceptable risk of microbial contamination to sterile drug products and undermine sterility assurance and patient safety.

This is a repeated observation from the inspection performed 09/16/2024 – 09/25/2024.

OBSERVATION 3

There is a failure to thoroughly review the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

Sterile Drug Manufacturing & 503B Outsourcing Facility

1. You have failed to determine root cause and implement effective corrective action for cracked media plates used for environmental monitoring (EM) analysis. You first identified this issue on

02/14/2024, where it then became an on-going issue. In February 2025, you initiated and closed a Corrective Action/Preventative Action (CAPA) without determining the root cause. Since closure of the CAPA, you have generated approximately nine (9) additional cracked plate events. Additionally, during 02/14/2024 – 02/25/2025, you generated approximately 87 events where you discarded and invalidated damaged media samples without incubating them. Discarded media plates largely include personnel monitoring samples that were collected to document the environmental conditions for media fills and the production of sterile drug products.

This is a repeated observation from the inspection performed 01/29/2024 – 02/09/2024

2. You have not determined suitability of your EM sampling process of using settle plates as opposed to (b) (4) contact plates for performing personnel (b) (4) monitoring. This change was implemented on 05/14/2024 in response to the cracked/damaged media plates on-going issue that was identified 02/14/2024.

Sterile Drug Manufacturing

3. You inappropriately invalidated a stability sample at (b) (4) for sterility for Provocholine (methacholine chloride) Solution for Inhalation 3mg/3 mL Lot#: 324261 Expiration: 07/31/2025. After incubating the (b) (4) canister at (b) (4) for (b) (4), you identified turbidity and thereby stopped the incubation process to proceed with subculturing for microbial identification. After failing to obtain viable growth on the subcultures, your quality unit concluded the turbidity observed did not contain viable microorganisms and ultimately invalidated the original sample without determining root cause for the turbidity. Per your written procedure MTM-SC-MB-6308 entitled, "Sterility Test Procedures" Revision: 39 Effective: 18-APR-2025, which is written based on USP <71>, samples are only invalidated for the four (4)

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	8/11/2025-8/22/2025* FEI NUMBER 3010892830

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Lou Kennedy , CEO	
FIRM NAME Nephron Sc Inc	STREET ADDRESS 4500 12th Street Ext
CITY, STATE, ZIP CODE, COUNTRY West Columbia, SC 29172-3025	TYPE ESTABLISHMENT INSPECTED Sterile Drug Manufacturing & 503B Outsourcing Facility

reasons:

a. "The data of the microbiological monitoring of the sterility test environment shows a fault.
b. A review of the testing procedure used during the test in question reveals a fault.
c. Microbial growth is found in the negative controls.
d. Upon determination of the identity of the micro-organisms isolated from the test, the growth of the species isolated may be ascribed unequivocally to faults with respect to the material and/or the technique used in conducting the sterility test."

Per your Director of Microbiology, the invalidated sample did not fall within any of these conditions.

OBSERVATION 4

Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Sterile Drug Manufacturing & 503B Outsourcing Facility

Specifically,

1. Your firm's visual inspection methods used for inhalation products are inadequate. Currently, this inspection process for visible particulates, discoloration or turbidity, a critical defect, includes inspecting (b) (4) (b) (4) units per (b) (4) and AQL sampling at level (b) (4). Your process has not been validated to ensure your inspection method can adequately detect these defects in all products effectively across all inspectors. In 2025, you generated approximately five (5) defects generated for particles, cloudy, white specks, and dark particles.

2. You do not have sound scientific justification for not performing visual inspection for identifying

AMENDMENT 1

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	8/11/2025-8/22/2025* FEI NUMBER 3010892830

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Lou Kennedy , CEO	
FIRM NAME Nephron Sc Inc	STREET ADDRESS 4500 12th Street Ext
CITY, STATE, ZIP CODE, COUNTRY West Columbia, SC 29172-3025	TYPE ESTABLISHMENT INSPECTED Sterile Drug Manufacturing & 503B Outsourcing Facility

particulates, a critical defect in (b) (4) ophthalmic products manufactured in your facility.

3. Your 100% visual inspection program used for inspecting injectable products is deficient for the following reasons:

   a. Your 100% visual inspection program does not challenge robust, worst-case conditions for identifying defects of varying criticality for sterile liquid injectable drug products manufactured in your facility. Currently, your program qualifies your inspectors for (b) (4) (b) (4) whereas your shift is for (b) (4) . Based on the validated batch sizes for products manufactured at your facility, inspectors are required to demonstrate competency in only a fraction of the units identified below. For example, for Sterile Water for Injection USP, inspectors are deemed qualified after evaluating a single tray containing (b) (4) units with 34 defects at 100% competency, whereas the theoretical batch size yields (b) (4) vials. This evaluation can occur up to (b) (4) times if failures are identified. Your visual inspection qualification does not demonstrate defect detection performance under actual production conditions.

AMENDMENT 1

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	8/11/2025-8/22/2025* FEI NUMBER 3010892830

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Lou Kennedy , CEO

FIRM NAME	STREET ADDRESS
Nephron Sc Inc	4500 12th Street Ext
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
West Columbia, SC 29172-3025	Sterile Drug Manufacturing & 503B Outsourcing Facility

Product	Filling Line / Equipment	Batch Size	Theoretical Yield
Albuterol Sulfate Inhalation Solution, 0.5%	(b) (4)		
1000 mL del Nido Cardioplegia Solution			
Labetalol Hydrochloride Injection, USP 20 mg/4 mL (5 mg/mL)			
Ketamine Hydrochloride Injection, USP 50 mg/5 mL (10 mg/mL)			
Neostigmine Methylsulfate Injection, USP 5 mg/5 mL (1 mg/1 mL)			
Ropivacaine Hydrochloride Injection, 1 g/500 mL (2 mg/mL)			
0.9% Sodium Chloride Injection, USP 500 mL			
Amino Acid Injection, 50 g/1000 mL (50 mg/mL)			
Fentanyl Citrate in 0.9% Sodium Chloride Injection, USP 2500 mcg/250 mL (10 mcg/mL)			
Nephron SC, LLC			
Product	**Filling Line / Equipment**	**Batch Size**	**Theoretical Yield**
Ipratropium Bromide 0.5 mg & Albuterol Sulfate 3.0 mg Inhalation Solution	(b) (4)		
Ipratropium Bromide 0.5 mg & Albuterol Sulfate 3.0 mg Inhalation Solution			
Albuterol Sulfate Inhalation Solution, 0.083%			
Albuterol Sulfate Inhalation Solution, 0.083%			
Budesonide Inhalation Suspension 0.25 mg/2 mL and 0.5 mg/2 mL			
Ipratropium Bromide Inhalation Solution 0.02%			
Albuterol Sulfate Inhalation Solution, 0.5%			
Albuterol Sulfate Inhalation Solution, 0.021% & 0.042%			
Upneeq (oxymetazoline hydrochloride opthalmic solution), 0.1%			
Racepinephrine Inhalation Solution, USP 2.25%			
Sterile Water for Injection, USP 5mL			
Provocholine (methacholine chloride) Inhalation Solution Kit			
Sodium Chloride Injection USP, 50 mL, 100 mL, 250 mL, and 500 mL			
Ketorolac Tromethamine Injection, USP 60 mg/2 mL			

* Inhalation product indicated on the product list are not included in the 100% visual inspection program SM 08/22/25

b. You did not establish a process to ensure created (b) (4) defects are not memorized during qualification administration. Visual inspectors who require requalification or fail qualification are retested using the same (b) (4) allowing for potential memorization of defective units. The same (b) (4) are reused for (b) (4) and (b) (4) attempts, as well as for (b) (4) visual inspection testing, increasing the risk that operators become familiar with known defects.

c. Your 100% visual inspection post-test qualification challenges inspector competency on product simulated (b) (4) created by visual inspection training supervisors rather than real product. You have not demonstrated these (b) (4) along with the created defects are equivalent to products manufactured in your facility and suitable for qualifying inspectors.

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Saundrea A Munroe, Investigator Rose L Jean-Mary, Investigator Kellia N Hicks, Investigator Simone E Pitts, National Expert	X Saundrea A Munroe Investigator Signed By: Saundrea A. Munroe - S Date Signed: 08-22-2025 20:21:05	8/22/2025

d. You have not qualified the inspection procedure used to measure overfill volumes for sterile prefilled syringes for your 100% manual visual inspection processes for 503B operations. Currently, you use the (b) (4) on (b) (4) syringes to create sleeves which are used as measuring devices. These sleeves are intended to measure volume that exceeds the (b) (4) applied the product's container closure system. These devices are uncontrolled and lack standardization.

e. The training of your 100% manual visual inspection trainers is inadequate in that they are deemed qualified on the (b) (4) they create. Additionally, per your Quality Operations Sr. Manager, of the (b) (4) trainers, one (1) is not qualified to perform 100% visual inspection on product and the other (b) (4) have not performed any visual inspection on finished products manufactured at your facility in at least six (6) years. All trainers have the responsibility of confirming or invalidating defects identified by inspectors during manufacturing operations. For 2025, you generated approximately eight (8) 503B complaints related to missing label, plastic particles, plastic in port and leaking bags.

OBSERVATION 5

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

Sterile Drug Manufacturing & 503B Outsourcing Facility

Specifically, your firm failed to follow procedures to ensure alarms impacting classified areas are promptly responded to, investigated, and corrected.

For example, during a walkthrough of the facility on 11 Aug 2025, we observed that the alarm for the (b) (4) (b) (4) had been alarming for a significant amount of time. The

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	8/11/2025-8/22/2025* FEI NUMBER 3010892830

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Lou Kennedy , CEO	
FIRM NAME Nephron Sc Inc	STREET ADDRESS 4500 12th Street Ext
CITY, STATE, ZIP CODE, COUNTRY West Columbia, SC 29172-3025	TYPE ESTABLISHMENT INSPECTED Sterile Drug Manufacturing & 503B Outsourcing Facility

Material Transfer Operator (b) (6), (b) present reported, "I don't do anything about alarms." The Corporate Chief Quality Officer confirmed the alarm had been active since that morning. She further reported that operators are trained to report and escalate alarms to management; however:

a. No operator reported or escalated the alarm.
b. No management oversight or monitoring of the alarm condition was evident.
c. No assessment was made regarding the potential impact of the alarm.
d. No investigation was initiated until we inquired.

Firm management later confirmed that the alarm indicated a differential pressure failure signifying loss of positive pressure from the ISO 7 area, which is the background area for (b) (4) operations, and had a controlled not classified (CNC) area.

Your firm failed to ensure that alarms critical to maintaining aseptic conditions were promptly addressed, escalated, and investigated. These deficiencies in alarm management and oversight create an unacceptable risk of microbial ingress and contamination of sterile products. The lack of effective alarm response undermines sterility assurance and patient safety.

This is a repeated observation from the inspection performed 01/29/2024 – 02/09/2024.

OBSERVATION 6

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Sterile Drug Manufacturing & 503B Outsourcing Facility ~~NPC & 503B Operations~~ SM 08/22/2025

Specifically,

AMENDMENT 1

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	8/11/2025-8/22/2025* FEI NUMBER 3010892830

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Lou Kennedy , CEO	
FIRM NAME Nephron Sc Inc	STREET ADDRESS 4500 12th Street Ext
CITY, STATE, ZIP CODE, COUNTRY West Columbia, SC 29172-3025	TYPE ESTABLISHMENT INSPECTED Sterile Drug Manufacturing & 503B Outsourcing Facility

A. There is a failure of the Quality Unit (QU) to review and approve (b) (4) (b) (4) that results in "abort" and "error." (b) (4) outcomes resulting in abort or error are documented and maintained in the (b) (4) and reviewed within the audit trails by Production management (b) (4) and (b) (4) These records are not reviewed by the QU or evaluated prior to batch disposition.

503B Outsourcing Operations ~~503B Operations~~ SM 08/22/2025

B. Your Quality Unit failed to adequately exercise its authority and responsibilities, including but not limited to, implementing effective procedures, and conducting adequate oversight to support the safety, effectiveness, and quality of the sterile drug products you manufacture. For example, but not limited to:

a. Your firm failed to exercise appropriate controls over computer or related systems to assure that only authorized personnel institute changes in master production and control records, or other records by maintaining oversight of (b) (4) (b) (4) Data, Backups, and Error Logs. For example, but not limited to, during the walkthrough of the facility on 12 Aug 2025, we observed the following:

1. Your Chief Technology Officer presented a file named "Exception.txt", which contained approximately 18,022 logged "Access Violation" errors from 04/17/2024–03/08/2025. Management acknowledged they were unaware of this error log. Vendor representatives were unable to explain the root cause or impact of the recurring access violations.

2. A file named "460133.err" contained additional error messages, described as the

AMENDMENT 1

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	8/11/2025-8/22/2025* FEI NUMBER 3010892830

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Lou Kennedy , CEO	
FIRM NAME Nephron Sc Inc	STREET ADDRESS 4500 12th Street Ext
CITY, STATE, ZIP CODE, COUNTRY West Columbia, SC 29172-3025	TYPE ESTABLISHMENT INSPECTED Sterile Drug Manufacturing & 503B Outsourcing Facility

raw data file for the Error Manager Viewer Machine Event Log. The "Exception.txt" log was reported to be ancillary to this error log.

3. Backups of (b) (4) (b) (4) data are only verified for existence (checked that the backup ran) but are not reviewed or evaluated for completeness or accuracy. Quality personnel have no oversight of these backups. Your Corporate Chief of Quality and Compliance confirmed that Quality was unaware of the Exception Log and does not review or verify the backups prior to batch release.

Your firm failed to ensure adequate control, oversight, and review of electronic records associated with the (b) (4) system, including audit trails and error logs. These failures create significant risk that data critical to batch release decisions may be incomplete, inaccurate, or not available for review. The lack of Quality Unit oversight over electronic data compromises sterility assurance and patient safety.

***DATES OF INSPECTION**

8/11/2025(Mon), 8/12/2025(Tue), 8/13/2025(Wed), 8/14/2025(Thu), 8/15/2025(Fri), 8/18/2025(Mon), 8/19/2025(Tue), 8/20/2025(Wed), 8/21/2025(Thu), 8/22/2025(Fri)

X Kellia N Hicks
Investigator
Signed By: KELLIA N. HICKS -S
Date Signed: 08-22-2025 20:21:49

X Rose L Jean-Mary
Investigator
Signed By: 2002859516
Date Signed: 08-22-2025 20:22:24

X Simone E Pitts
National Expert
Signed By: Simone E. Pitts -S
Date Signed: 08-22-2025 20:23:05

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Saundrea A Munroe, Investigator Rose L Jean-Mary, Investigator Kellia N Hicks, Investigator Simone E Pitts, National Expert	X Saundrea A Munroe Investigator Signed By: Saundrea A. Munroe -S Date Signed: 08-22-2025 20:21:05	8/22/2025

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."