DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768 ORAPHARM2_RESPONSES@fda.hhs.gov	9/16/2024-9/25/2024* FEI NUMBER 3011158388

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

FIRM NAME	STREET ADDRESS
Nephron Sterile Compounding Center LLC	4500 12th Street Ext
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
West Columbia, SC 29172-3025	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:
Production System

OBSERVATION 1

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

Specifically,

A. Your (b) (4) in room 282G is designed that the syringes to be filled enter the syringe track (b) (4) and the exposed syringe tip are facing to the (b) (4) (or the syringe track) without exposure to first air. The syringe tip pass through the syringe track at a clearance of (b) (4) at the closest point. These syringes with the movement of the line, are (b) (4), create (b) (4) in the air and making (b) (4) circulate around the exposed syringe tip. The product filled in (b) (4) are Phenylephrine HCl Injection USP 1mg/ 10mL; Succinylcholine Chloride Injection 200 mg/ 10mL; Ketamine Hydrochloride Injection, USP 50mg/ 5mL; and Rocuronium Bromide 50 mg/ 5mL.

B. (b) (4) were identified in your comprehensive resin ID list from 2022 thru 09/2024. Although the bioburden level for these organisms is below your (b) (4) CFU/g threshold, you currently have no requirement for objectionable eukaryotic organisms, only prokaryotes. These genera may be considered objectionable organisms due to their capacity to produce mycotoxins that can withstand (b) (4) for more than (b) (4). Your BFS machines function at (b) (4) for an exposure time of not more than (b) (4). No risk assessment has

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Joanne E King, Investigator Veronica Fuentes, Investigator Homero W Aguilar, Microbiologist	X Veronica Fuentes Investigator Signed By: Veronica Fuentes -S Date Signed: 09-25-2024 18:14:37	9/25/2024

been performed to determine the potential for objectionable eukaryotic organisms and the impact they may have throughout the manufacturing process.

C. Your formulation processes and process validations for the following products: Succinylcholine Chloride Injection 200 mg/ 10mL, Rocuronium Bromide 50 mg/ 5mL, Phenylephrine HCl Injection, USP 1mg/ 10mL, Ketamine Hydrochloride Injection, USP 50mg/5mL, and Del Nido Cardioplegia Solution, require (b) (4) pharmaceutical grade (b) (4). You test these (b) (4) following (b) (4), if your (b) (4) does not pass the (b) (4), you (b) (4) the (b) (4) and test the (b) (4) for a second occasion. If the second testing of the (b) (4) (b) (4) fails, you test the (b) (4). You will not investigate if that (b) (4) passes the (b) (4) as to why the (b) (4) failed. This was observed with the (b) (4) Del Nido Cardioplegia Solution lot (b) (4).

Additionally, you do not test the (b) (4) if the (b) (4) passes the (b) (4).

This is a repeat citation from inspections dated 11/2022-02/2023, and 02/2024.

OBSERVATION 2

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

Specifically, your Non-Viable Environmental Monitoring is not performed at a representative interval during your syringe filling operation that would reflect any potential excursion of particulate. This monitoring is performed at the (b) (4) of the batch and then at the (b) (4) of the operational shift (which lasts (b) (4)). Additionally, during this process you do not perform Passive Air Monitoring in your (b) (4). This was observed during the syringe filling Phenylephrine HCl Injection USP 1mg/ 10mL lot (b) (4)

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Quality System

OBSERVATION 3

There is a failure to thoroughly review any unexplained discrepancy and 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,

A. MedWatch complaint 23673255 received on 3/25/2024 was for a complaint made by a customer that was a hospital pharmacy director after observing dark particles in one blow fill seal vial (BFS) of albuterol sulfate 0.083% lot (b) (4) expiration 2/28/2025 manufactured on (b) (4). This one unopened complaint 3 ml vial and 30 others unopened BFS vials each containing 3ml from the same lot were returned to your firm. The returned vial containing the particle was tested and found to be out of specification (OOS) for the impurity (b) (4) and (b) (4) an identified unknown impurity. The other 30 returned 3 ml vials with no particles from the hospital (FAR-24001) were not tested for impurities to identify if the determined cause of the particle and impurities was the same. The two impurities were not part of the medical risk assessment performed because of this investigation. The particle was determined to be composed of 83.97 % polyethylene propylene diene. The most probable root cause of the event is (b) (4) .

   In addition, a sterility test was also performed only on the one BFS vial containing the particle and the sterility test did not include the growth media (b) (4) used to culture anaerobic and aerobic bacteria.

B. MedWatch complaint 23522845 received on 2/13/2024 was for a complaint made by a consumer that was a parent for a child given albuterol sulfate inhalation solution 0.083% lot (b) (4) expiration 4/30/2025 manufactured on (b) (4) NDC 0487-9501-03. The complaint was for a strong smell and odor from some of the BFS lots when used. The odor was described

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as a coconut smell or air freshener smell, and this permeated the child's hair and clothing and was identified by both parents as well as the child when administered. 43 BFS of the complaint vials were returned by the parent. Other than the review of the complaint log, batch record, and certificate of analysis for this lot no other actions were taken to identify the suspect odor and the investigation was closed by Regulatory Affairs Management and the QA Designee. The complaint vials were thrown away.

Equipment and Facilities System

OBSERVATION 4

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

Specifically, on 9/17/2024 during the manufacturing of del Nido cardioplegia solution 1000 ml lots (b) (4) and (b) (4) we observed that changes and readings of differential air pressure were not available to employees during aseptic operations for example:

A. The ISO-8 room M108 located on the mezzanine where hand washing is performed and the ISO-7 room (b) (4) to this where sterile gowning is performed there was no alarm, light, or device providing an indication and measurement of a change in differential pressure which occurs when moving from one room classification to the next.

B. The ISO-7 formulation room M190 which contains the formulation vessel (b) (4) where components are charged into the top of the (b) (4) (b) (4) and where (b) (4) is performed and the filling room M123 which contains an ISO5 (b) (4) laminar flow hood where sterile bulk del Nido cardioplegia solution is filled into 1000 ml sterile IV bags there was no alarm, light, or device with a observable measurement such as a digital display or magnehelic gauge providing an indication and measurement of a change in differential pressure which

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occurs when moving from the ISO-7 corridors and into these rooms and when the doors to these rooms were opened.

C. The ISO-5 room 282G which contains the pre-filled syringe (b) (4) filling machine located on the second floor of the manufacturing building and connected to the ISO-7 282 Suite where commercially sterile syringes and syringe caps are loaded into the (b) (4) for filling of 10 ml prefilled syringes with phenylephrine HCL for injection USP 1 mg/10 ml (100 mcg/ml) lot (b) (4) On 9/23/2024, we observed that the door leading from the ISO-7 282 Suite to the ISO 5 controlled room 282G that there was no alarm, light, or device with an observable measurement such as a digital display or magnehelic gauge providing an indication and measurement of a change in differential pressure which occurs when moving from the ISO-7 control room area and into the ISO5 and when the doors to these rooms were opened.

OBSERVATION 5

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

Specifically, on 9/17/2024 while in the ISO8 room M108 and the gowning room and corridor beyond both ISO-7 we observed visible residue on the floors that were both red and white of approximately 3 by 1 1/2 feet. These floors also appeared to have possible surface damage which could prevent appropriate cleaning and sanitization all leading to your aseptic processing suites such as M190 and M123.

***DATES OF INSPECTION**

9/16/2024(Mon), 9/17/2024(Tue), 9/18/2024(Wed), 9/19/2024(Thu), 9/20/2024(Fri), 9/23/2024(Mon), 9/24/2024(Tue), 9/25/2024(Wed)

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X Homero W Aguilar
Microbiologist
Signed By: Homero W. Aguilar -S
Date Signed: 09-25-2024 18:15:12

X Joanne E King
Investigator
Signed By: 1300174867
Date Signed: 09-25-2024 18:15:42

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Joanne E King, Investigator
Veronica Fuentes, Investigator
Homero W Aguilar, Microbiologist

X Veronica Fuentes
Investigator
Signed By: Veronica Fuentes -S
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9/25/2024

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."