DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street Cincinnati, OH 45202 (513)322-0700 Fax:(513)679-2772	11/8/2022-12/2/2022* FEI NUMBER 3010247115

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Randy G. McClure, Warehouse Manager

FIRM NAME	STREET ADDRESS
Nephron Pharmaceuticals	78 Spruce St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Murray, KY 42071-3505	Warehouse

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

There is no quality control unit.

Specifically,

Your firm does not have a quality control unit even though quality activities are taking place such as (b) (4) retain examination. The most recent retain exam was conducted by warehouse personnel on 11/12/2021.

OBSERVATION 2

Reserve samples from representative sample lots or batches of drug products selected by acceptable statistical procedures are not examined visually at least once a year for evidence of deterioration.

Specifically,

Your firm does not have a documented scientific justification for not inspecting vials that are packaged in a secondary foil wrapper. According to procedure, SOP-SC-QA-3251 titled, "Finished Product (b) (4) Examination of Retained Samples", QA or designee will "visually inspect the retained finished product samples for (b) (4) ". Additionally, the procedure indicates that (b) (4) are attributes to be examined. Your personnel only inspect retain samples of sterile inhalation/injectable products packaged in sealed secondary foil pouches for leakage during the (b) (4) retain audit. Approximately (b) (4) vials were packaged in sealed foil during

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the (b) (4) inspection on 11/12/2021. The sealed foil package inhibits direct inspection of the finished product vials for defects. Not a single foil pouch is opened for examination of the product vial during the retain exam.

The inspection on 11/12/2021 included but is not limited to the following products: Ipratropium Bromide and Albuterol Sulfate 3mg/3mL .5mg/3mL – lots 128071, 128121, and 128141; Asthmanefrin, 11.25 mg/.5mL – lots 126111 and 126231; and Racepinephrine Hydrochloride 11.25mg/.5mL – lots 126101 and 126121.

OBSERVATION 3

Employees are not given training in written procedures required by current good manufacturing practice regulations.

Specifically,

The personnel performing the (b) (4) retain inspection are not adequately trained. The warehouse personnel conducted the (b) (4) retain inspection on 11/12/2021, however, finished product inspection training was not performed until 4/14/2022. Additionally, only read and understand training has been given to the warehouse personnel for the "Finished Product (b) (4) Examination of Retained Samples" procedure, SOP-SC-QA-3251.

Sealed foil pouches containing approximately (b) (4) vials, (b) (4) non-foil sealed sterile bottles/vials, and an additional (b) (4) IV bags were inspected during the retain sample audit performed on 11/12/2021 in a single shift by a single employee. The personnel performing the audit have also not been qualified to demonstrate their ability to detect defects such as discoloration, particulates, or leakage. This inspection included but is not limited to the following products: Ipratropium Bromide and Albuterol Sulfate 3mg/3mL .5mg/3mL - lots 128071, 128121, and 128141; Asthmanefrin, 11.25 mg/.5mL - lots 126111

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and 126231; and Racepinephrine Hydrochloride 11.25mg/.5mL - lots 126101 and 126121.

OBSERVATION 4

Drug products are not stored under appropriate conditions of humidity and light so that their identity, strength, quality, and purity are not affected.

Specifically,

Your firm did not establish worst case monitoring locations for the temperature monitoring done in your warehouse. The warehouse temperature mapping study is inadequate for the storage conditions listed on your finished drug product label. Many of your firm's finished drug products are labeled for storage between 2-25 degrees C (36-77 F). According to your warehouse manager, the current warehouse temperature specifications are (b) (4) degrees F. The temperature mapping study consisted of a (b) (4) study with (b) (4) monitors throughout the warehouse in January of 2020. An additional 3-year review of the temperature data from the (b) (4) monitors currently in place was also performed, however, these monitor locations are not based on a scientific justification. Your firm does not have data to support the temperature sensor locations and heights chosen to demonstrate control throughout the warehouse during seasonal temperature fluctuations.

Products stored in your warehouse include but are not limited to: Racepinephrine Inhalation Solution 2.25% lot 226731, exp 3/2024; Albuterol Sulfate Inhalation Solution 0.042% lot 227551, exp 2/2024; and Albuterol Sulfate Inhalation Solution 0.083% lot 229401, exp 7/2024.

*DATES OF INSPECTION

11/08/2022(Tue), 11/09/2022(Wed), 11/30/2022(Wed), 12/01/2022(Thu), 12/02/2022(Fri)

	EMPLOYEE(S) SIGNATURE		DATE ISSUED
SEE REVERSE OF THIS PAGE	Logan T Williams, Investigator Robert J Ham, Investigator	X Logan T. Williams	12/2/2022

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."