DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse Rm900 200 Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875 ORAPHARM1_RESPONSES@fda.hhs.gov	7/15/2024-8/2/2024* FEI NUMBER 3022250654

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Pardeep K. Gupta, Pharmacist-In-Charge

FIRM NAME	STREET ADDRESS
ProRx LLC	619 Jeffers Cir
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Exton, PA 19341-2540	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, written and followed.

Specifically,

A) On 07/25/2024, during the production of Semaglutide 2.5mg/ml, Lot# (b) (4) Exp. 01/24/2025, your firm's operator was observed filling sterile drug product in a manner that directly blocked first pass air over uncapped and filled vials of Semaglutide 2.5 mg/ml. Additionally, your Pharmacist-in-Charge (PIC), was observed rapidly prodding a pile of sterilized rubber caps with forceps, in an attempt to dislodge them, inside of the ISO 5 Biosafety Cabinet (BSC) Hood-1, Asset #A-051, near uncapped filled vials of Semaglutide 2.5 mg/ml.

B) On 07/16/2024, your firm's PIC was observed exposing their bare hands in the ISO 5 BCS hood to don sterile gloves after the BSC was cleaned and prior to manufacturing sterile drug production, Vancomycin 25mg/ml, Lot: (b) (4), Exp.: 08/02/2024.

C) On 07/25/2024, your firm's PIC was observed bending down on the floor, on their hands and knees, inside of the ISO 7 Anteroom. Your firm's PIC then sprayed only their gloves with (b) (4) and proceeded to produce Semaglutide 2.5mg/ml, Lot# (b) (4), Exp: 01/24/2025.

D) Your firm's ISO 5 BSC is powered off when not in use and during the cleaning and disinfection

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process prior to aseptic drug production. Prior to manufacturing sterile drug product, the ISO 5 BSC work bench surface area is only required to be disinfected with a (b) (4) while the BSC is powered off. There is no assurance that contamination is not introduced when the BSC powered off. Furthermore, your firm has no scientific rationale for cleaning and disinfecting the BSC unit while powered off.

E) Your firm's wipes used in the cleaning and disinfecting of the surfaces inside the ISO 5 BSC and the ISO 7 Buffer room, are purchased non-sterile and then (b) (4) by using a non-validated sterilization cycle in a non-ISO 5 environment. The wipes are then dried in a (b) (4) (b) (4) which is not in an ISO 5 environment and placed into plastic storage bins, which your firm cannot provide assurance are a sterile environment. The plastic storage bin containing the (b) (4) wipes is housed inside of the ISO 7 Buffer room. Additionally, these (b) (4) wipes can be used for up to (b) (4) with no scientific justification.

F) Your firm's HEPA filters are only certified annually instead of every 6 months and is also not performed under dynamic conditions.

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic and sterilization process.

Specifically, your firm's media fill program is inadequate as it does not provide an assurance that your staff can manufacture drug product under aseptic conditions. The following deficiencies were identified:

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A) Media fills are not performed in accordance with a written procedure, ProSOP-B052, *SOP For Media Fill*.

B) Your media fill studies fail to ensure that all simulated aseptic manufacturing operations are represented to include the worst-case scenario (number of vials filled/ batch size/ volume/ time/ interventions) in order to assess the potential for batch contamination. There have been (b) (4) media fills studies performed at your site to date (2/28/2023, 4/2/2023, 4/2/2023, 4/16/2023, 1/12/2024, and 4/11/2024). For example, your firm manufactured a batch size of (b) (4) units for Semaglutide 2.5mg/ml on 01/18/2024, when your completed media fill study was only for (b) (4) units, and a batch size of (b) (4) units for Tirzepatide 60mg/3ml on 06/10/2024, when your most recent completed media fill study only entailed (b) (4) units. Your firm uses an ISO 5 BSC Hood-1 in Cleanroom (b) (4) for filling sterile Semaglutide 5mg/2ml, Tirzepatide 60mg/3ml, Tobramycin 14mg/ml, Vancomycin 25mg/ml, Disodium EDTA 2%, and Dexamethasone Sodium Phosphate 24mg/ml.

C) Your firm does not have scientific justification for only conducting media fills in vials and not incorporating other container closure system such as, eye drop containers to assess your aseptic filling operations within your (b) (4) Biosafety Cabinet Hood 1.

D) Your firm failed to capture any types of environmental and personnel monitoring during all media fills performed at your facility, i.e. viable air monitoring, viable surface monitoring, non- viable air monitoring, and personnel monitoring.

E) Your firm failed to observe all vials during the (b) (4) incubation period for the media fill performed on 04/11/2024 when (b) (4) vials were filled and only (b) (4) (b) (4) (b) (4) vials were chosen to see if turbidity was present. Additionally, there is no scientific justification for not observing all (b) (4) incubated units.

F) Your firm failed to ensure that the purchased media powder used for media fill studies is

growth promoted and suitable for its intended use, prior to use.

G) Your firm's procedure, ProSOP-B052, *SOP For Media Fill*, fails to quantify the number of times an employee should requalify each year and what constitutes a media fill study failure if turbidity is observed in one or more units.

OBSERVATION 3

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

Specifically,

A) Your firm failed to capture any types of environmental and personnel monitoring during all sterile drug production performed at your facility. There have been approximately (b) (4) batches of sterile drug products produced onsite since August 2023 without environmental or personnel monitoring performed during production.

(i) Environmental monitoring, which you only perform (b) (4), is not performed under dynamic conditions.

(ii) Surface and viable air monitoring plates are only incubated for a total of (b) (4). The existing incubation temperature and duration for media used in environmental monitoring does not account for the detection of fungi (i.e. yeast and molds). Your firm does not have any scientific justification to ensure that the incubation period used to incubate your viable (b) (4) plates is adequate to capture objectionable organisms.

(iii) There has not been any personnel monitoring conducted and documented for your personnel that operate inside of the ISO 5 BSC environment to produce sterile drug product.

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(iv) Additionally, your firm's procedure, ProSOP-B033, *SOP For Room Monitoring Process at ProRx,* lists the action level for viable surface sample at (b) (4) colonies forming units per sampling device, which is not appropriate for an ISO 5 environment.

B) Smoke studies are not performed under dynamic conditions to demonstrate maintenance of laminar air flow within your ISO 5 Biosafety Cabinet when used to aseptically process sterile drug products.

C) Your firm does not have a defined minimum differential pressure between ISO 7 spaces and unclassified spaces, to ensure that contamination risk is minimized. Additionally, there is not any continuous monitoring of clean room spaces and the core area before entering your anteroom for pressure differential, temperature, and humidity.

OBSERVATION 4

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

Specifically,

A) Your firm has not implemented CGMP systems with quality oversight, nor do you have personnel with CGMP knowledge to oversee these systems. The following deficiencies were observed, indicating inadequate oversight during quality control operations, manufacturing operations, and release procedures for drug products. The following systemic deficiencies were noted:

- Your firm fails to ensure meta data generated is backed up on computer systems.
- Your firm fails to assess, document, mitigate risk for, track, and approve changes that might impact drug product quality, i.e. changing API vendors, batch sizes, formulation changes, and fill volumes.
- Your firm fails to have processes and procedures for change control, recall, stability studies,

process validation, supplier verification, preventative maintenance, equipment validation (IP/OP/QP), etc.

Furthermore, your firm's quality unit is comprised of one individual who is responsible and holds the authority to oversee all quality-related activities but also functions as part of the production staff that manufactures sterile and non-sterile drug products. According to your firm's Quality Manual, QM-001, "the Pharmacist in-charge, serves as the quality manager, who evaluates and identifies problems and then delegate duties to others," that being the limited production staff that performs quality related functions such as review and approve sterile drug products for release, packaging and shipping, and laboratory testing.

B) Your firm does not have an visual inspection program. The following deficiencies were noted:

(i) Your firm does not have a visual inspection program that consists of a contrasting background, appropriate lighting, and a qualified visual inspection sample defect kit used to train visual inspectors.

(ii) Your firm has no evidence in your batch records that visual inspections are performed for your sterile drug products prior to release for distribution. For example, on 07/25/2024, your employee did not adequately conduct a visual inspection by not using a contrasting background in appropriate lighting, (b) (4) the vial to disturb the drug product, and by not inspecting it for a set length of time during the labeling process of the clear glass filled vials of Semaglutide 2.5mg/ml, Lot (b) (4) Exp: 01/25/2024. Additionally, your firm does not have a written procedure for visual inspection process and there is no documented training that also assesses an eye examination and length of time inspections are performed.

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OBSERVATION 5

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) Your firm's media fill performed on 04/2/2023, had one turbid vial out of (b) (4) filled vials filled. Your firm's quality unit did not perform an investigation into the root cause, nor did you make an attempt identify the organism(s) in the turbid vial. The media fill performed on 04/02/2023 was not classified as a sterility failure; however, another media fill performed on 04/16/2023 was conducted due to the turbid vial. Incubated vials from the media fill performed on 04/16/2023 were only observed on day 7 for turbidity and were not observed for turbidity after (b) (4) of incubation. Your firm accepted the results of the media fill and failed to document results of your incubated vials for (b) (4) as required by SOP-052, *Media Fills*. There is no justification for failing to conduct an investigation and implement corrective and preventive actions (CAPA) related to the failed media fill.

B) Your firm failed to investigate a potency Out of Specification (OOS) result to evaluate the potential risk and quality impact. For example, your firm produced sterile drug product Semaglutide 2.5mg/ml, Lot # (b) (4) Exp: 09/25/2024, that yielded an OOS potency result of 2.78mg/ml (specification of (b) (4)). Your firm did not investigate the cause of this potency failure that occurred on 03/26/24.

OBSERVATION 6

Clothing of personnel engaged in the manufacturing, processing, packing and holding of drug products is not appropriate for the duties they perform.

Specifically,

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A) On 07/16/2024 and 07/25/2024, your operators were observed donning non-sterile, disposable lab coats over their street clothing, and wearing disposable shoe covers to enter the ISO 7 Buffer room to aseptically fill sterile drug products, without using sterile sleeves inside of the ISO 5 BSC environment, i.e. Vancomycin 24mg/ml, Lot (b) (4) Exp: 08/02/2024 and Semaglutide 2.5mg/ml, Lot (b) (4), Exp: 01/24/2025.

B) On 07/16/2024 and 07/25/2024, your operators were observed working in the ISO 5 BSC and ISO 7 Buffer room with inadequate gowning that exposed the forehead, neck, and eyes. Furthermore, disposable non-sterile laboratory coats and non-sterile cloth booties are laundered by staff at a local establishment and subsequently used again inside of the cleanroom areas.

C) There is no gowning qualification program at your facility.

OBSERVATION 7

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

Specifically, your firm has not performed a disinfectant study using (b) (4) solution, nor do you follow the manufacturer's direction for disinfection, which indicates that a wet contact time of (b) (4) is required to achieve disinfection efficacy when using sterile (b) (4) in a Cleanroom environments, ISO 5 and ISO 7. On 07/25/2024, we observed your firm only allow a wet contact time of five minutes before initiating the process to perform aseptic operations. Your firm is not ensuring that contact time are met to reach disinfection efficacy when wiping items into the cleanroom area. Additionally, the non- pharmaceutical grade (b) (4) used as a (b) (4) sporicidal agent is only (b) (4) to clean the ISO 5 BSC, and the walls and floors of the ISO 7 Buffer Room and ISO 7 Anteroom. This strength as a sporicidal cleaning agent in the aseptic processing area is not supported by any scientific justification.

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OBSERVATION 8

Buildings used in the manufacture, processing, packing or holding of drug products are not free of infestation by rodents, birds insects, and other vermin.

Specifically, your firm does not have an established pest control program. On 07/25/2024, a flying insect was observed on the walls and ceilings of the ISO 7 Anteroom and on the door inside of the ISO 7 Buffer Room, approximately 10 feet from the ISO 5 Biosafety Cabinet hood used for sterile drug processing. Additionally, there were approximately 4 crawling insects found in the perimeter area of your cleanroom that houses the HVAC system.

OBSERVATION 9

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use and cleaning and maintenance.

Specifically, your firm failed to perform protocol driven equipment qualification studies for the following equipment:

- (b) (4), A-027, used for sterilizing materials to be used in the cleanroom.
- (b) (4) A-025, used for drying the materials that exit the (b) (4) after the sterilization process;
- (b) (4) Incubator, A-028, used for incubating environmental monitoring samples;
- (b) (4) pumps, A-091 for (b) (4) operation and A-077 for filling operation, used for transferring various liquids;

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- HPLC, A-001, used for testing for potency for sterile drug products,
- Refrigerator/ Freezer Units, A-030 and A-095, used for the storage of quarantined drug products prior to QA approval and A-100, which is the refrigerator for finished drug product prior to shipping;
- (b) (4) Biosafety Cabinet, A-051, which functions as an ISO 5 classified area for preparation of sterile drug products.
- HVAC, used to supply the cleanroom with adequate temperature and humidity,
- (b) (4) system, used on the HPLC and for cleaning in the cleanroom.

OBSERVATION 10

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically, your firm does not have a written stability program that supports the expiration of your sterile and non-sterile drug products. Your firm extended the beyond-use-dates (BUD) for Semaglutide and Tirzepatide from a 30-day BUD to a 6-months with no supporting stability studies or documented scientifically sound rationale.

OBSERVATION 11

Reports of analysis from component suppliers are accepted in lieu of testing each component for conformity with all appropriate written specifications, without performing at least one specific identity test on each component and establishing the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.

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Specifically,

A) Your firm has never formally qualified any of the API suppliers you use in the production of drug products. Your firm has no SOP for formally qualifying API suppliers. The following batches of Tirzepatide (b) (4) , Expiry12/09/2024, and (b) (4) Expiry 11/21/2024, were made with the active ingredient Tirzepatide which was obtained by an unqualified external API supplier. Additionally, your firm imported and used Semaglutide API, for production of sterile drug products from a vendor that had not been qualified.

B) Your firm does not perform identification testing for all incoming lots of APIs used in non-sterile and sterile drug products.

OBSERVATION 12

The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Specifically,

A) The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A). The following information is not found on your drug product labels:

a. The statement "This is a compounded drug";

b. The full address of the outsourcing facility;

c. The dosage form;

d. The statement "Office Use Only" for drugs dispensed or distributed other than pursuant

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to a prescription for an individual identified patient;

e. A list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient.

Examples of your drug product labels that do not contain this information:

- Semaglutide 5 mg/2 mL (2.5 mg/mL) 2 mL Multiple Dose Vial
- Tirzepetide 60 mg/3mL (20gm/mL) 3mL Multiple Dose Vial

B) The containers of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(B). Specifically, your containers do not include the following information:

a. Information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088;

Examples of your container labels that do not contain this information:

- Semaglutide 5 mg/2 mL (2.5 mg/mL) 2 mL Multiple Dose Vial
- Tirzepetide 60 mg/3mL (20gm/mL) 3mL Multiple Dose Vial

OBSERVATION 13

Your outsourcing facility did not submit a report to FDA upon initial registration as an outsourcing facility identifying the drugs compounded during the previous six month period.

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Specifically, your outsourcing facility did not submit required products reports upon initial registration of your facility on April 27, 2022 in June 2022 and December 2022.

***DATES OF INSPECTION**

7/15/2024(Mon), 7/16/2024(Tue), 7/17/2024(Wed), 7/18/2024(Thu), 7/25/2024(Thu), 7/26/2024(Fri), 8/01/2024(Thu), 8/02/2024(Fri)

X Jazmine N Brown
Investigator
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Date Signed: 08-02-2024 15:03:41

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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."