DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900 Fax:(973)331-4969 ORAPHARM1_RESPONSES@fda.hhs.gov	7/11/2022-8/5/2022* FEI NUMBER 3003348498

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Ms. Suja Alum, PharmD, General Manager and Pharmacist-in-Charge

FIRM NAME	STREET ADDRESS
ImprimisRx NJ	1705 Route 46 West, Ste 4
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Ledgewood, NJ 07852-9720	Producer of sterile and non-sterile drug products

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

The ISO 5 classified aseptic processing areas had visibly dirty equipment or surface.

Specifically, on July 11, 2022, we observed dark orange staining on the HEPA filters in the back of the (b) (4) LAFH NJ-LAFH (b) (4) in the sterile production suite filling room. These HEPA filters supply the ISO 5 classified production area with (b) (4) HEPA airflow. On July 29, 2022, we observed the production of "EDETATE DISODIUM INJECTION", lot 07292022@ (b) (4) in this hood and noted that the discoloration was not removed prior to, during, or after production. Additionally, (b) (4) batches of products produced within this hood from February 8, 2022, to July 8, 2022, and currently within expiry, have been distributed under respective prescriptions. For example, see the table below for prescriptions distributed for three different batches:

Product	Batch Number	Rx Numbers
ASCORBIC ACID (NON-CORN SOURCE) PF 100ML 50L BATCH (500)MG/ML INJECTABLE	(b) (4)	(b) (6)
VITAMIN B-COMPLEX PRESERVATIVE-FREE 100MG-2MG-2MG-100MG-2MG INJECTABLE	(b) (4)	
DMPS SODIUM PF 50 MG/ML INJECTABLE 50 MG/ML INJECTABLE	(b) (4)	

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EMPLOYEE(S) SIGNATURE

Sena G Dissmeyer, Investigator
Tekalign Wondimu, Investigator
Amy N Chen, Investigator

X Sena G Dissmeyer Investigator Signed By: Sena G. Dissmeyer -S Date Signed: 08-05-2022 17:05:58

DATE ISSUED
8/5/2022

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OBSERVATION 2

Personnel did not disinfect and change gloves frequently enough to prevent contamination.

Specifically, on July 12, 2022, production technician (b) (6) was observed multiple times using (b) (6) gloved hand to handle items outside of ISO 5 classified (b) (4) LAFW hood NJ-LAFH(b) (4) and then subsequently handling items inside the hood without resanitizing (b) (6) gloves. For example, in two instances, (b) (6) sprayed (b) (6) hands with (b) (4)) then grabbed onto a chair and then reinsert (b) (6) hand underneath the ISO 5 hood handling products without resanitizing (b) (6) gloves. In another instance, (b) (6) sprayed (b) (6) gloved hands with (b) (4), then moved the plastic bin containing the empty eye drop vials and then went right underneath the ISO 5 hood to handle products, again, without resanitizing (b) (6) gloves with (b) (4). These occurred during the production of "TIMOLOL - BRIMONIDINE -DORZOLAMIDE P-F OPTH (0.5/0.15/2) % SOLUTION", lot 07122022@(b) (4)

OBSERVATION 3

Materials or supplies were not disinfected prior to entering the aseptic processing areas.

Specifically, during the production of "TIMOLOL - BRIMONIDINE - DORZOLAMIDE P-F OPTH (0.5/0.15/2) % SOLUTION" ophthalmic drops, lot 07122022@(b) (4) and "EDTA DISODIUM PF 150 MG/ML INJECTABLE", lot 07292022@(b) (4) on July 12 and 29, 2022, respectively, production technician (b) (6) inadequately sanitized items before bringing them from the ISO 7 classified filling room into the respective ISO 5 classified hood. The items, such as bagged vials, bottles, and caps, were sprayed with (b) (4) while (b) (4) atop a stainless-steel table, placing sanitized surfaces back onto the tabletop as the opposite sides were sprayed, and they were not sprayed or wiped again before crossing the threshold into the higher classification space. The stainless-steel table was sanitized immediately prior to production and utilized repeatedly for the purpose of sanitizing items over the course of the batch production, lasting approximately a few hours.

OBSERVATION 4

The use of sporicidal agents in the cleanrooms and ISO 5 classified aseptic processing area was inadequate.

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	Sena G Dissmeyer, Investigator Tekalign Wondimu, Investigator Amy N Chen, Investigator	X Sena G Dissmeyer Investigator Signed By: Sena G. Dissmeyer -S Date Signed: 08-05-2022 17:05:58	8/5/2022

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Specifically, during "(b) (4) cleaning" operations of the sterile suite on July 27 and 28, 2022, we observed the following:

A. The interior ceiling of the ISO 5 classified (b) (4) LAFH, hood NJ-LAFH(b) (4) was not cleaned at any point during the (b) (4) cleaning process with a sporicidal or sanitizing agent. Production technicians (b) (6) and (b) (6) explained that the surface is not ever cleaned or wiped, including the "plastic" grate covering the HEPA filters, as explained by (b) (6)

B. On July 27, 2022, while production technician (b) (6) was cleaning the walls of the ISO 7 classified filling room with a mop head and either a detergent or sporicidal agent, he mopped around areas where items were protruding (i.e. fire alarm, outlet covers, and door handle) and not the items themselves. Those items were not cleaned at any point in the (b) (4) cleaning process. (b) (6) later explained that the protruding items should be cleaned during the (b) (4) cleaning process.

C. During the (b) (4) cleaning process of the ISO 7 classified filling room on July 27, 2022, floor coving was not cleaned with a detergent or sporicidal agent. Production technicians (b) (6) and (b) (6) used a mop head to clean the wall in a downward motion but stopped right where the floor coving starts, about three inches in height from the floor, at the junction of where the wall meets the floor. Per (b) (6) the wall cleaning should stop at the floor coving and the coving should be cleaned during the floor mopping. The floor mopping observed on July 27, 2022, did not include cleaning of the floor coving.

D. (b) (4) wrapped items, such as glass beakers and stainless-steel bowls, in the ISO 7 classified "compounding room" were not stored in a manner to mitigate potential contamination of the outer (b) (4) layer during the sterile suite shutdown (b) (4), or sanitized at any point during the subsequent (b) (4) cleaning process. The (b) (4) wrapped items remained in the room as other surfaces were cleaned and the room was subsequently used for production on July 29, 2022.

OBSERVATION 5

Your facility design allowed the influx of poor quality air into a higher classified area.

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Specifically, on July 11, 2022, we observed two fire extinguishing sprinkler system heads, located in the ceiling of the ISO 7 classified filling room, hanging down from the ceiling, leaving an approximately one-centimeter gap in which air from the unclassified area above the ceiling could flow into the ISO 7 classified filling room. One of the sprinkler heads was missing a rubber gasket used to seal any opening between the sprinkler head cap and ceiling tile.

OBSERVATION 6

The segregated production areas surrounding the ISO 5 classified aseptic processing area contained dust-collecting overhangs without adequate and frequent cleaning.

Specifically,

A. On July 11, 2022, we observed two fire extinguishing sprinkler system heads, located in the ceiling of the ISO 7 classified filling room, hanging down from the ceiling, which creates difficult to clean surfaces around the objects protruding from the ceiling tiles.

B. The ceiling of the ISO 7 classified production area contains difficult to clean surfaces. On July 11, 12, and 13, 2022, we observed fiber-like particles, approximately a couple inches in length each, hanging from ceiling of the ISO 7 classified filling room and ISO 7 classified gowning room. On July 27, 2022, while production technician (b) (6) was cleaning the ceiling of the ISO 7 classified filling room, caulking from the ceiling tiles, approximately a couple inches in length each, started to peel away in four instances. In two of these instances, the pealed caulking was pushed back intact with the mop head, and in two cases the caulking peeled away and fell to the floor in the ISO 7 classified filling room.

OBSERVATION 7

Non-microbial contamination was observed in your production area.

Specifically,

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A. There is no assurance that your cleaning process removes product and cleaning agent residue from your reusable glassware and utensils used in non-sterile production areas. Liquid hand soap, "FOAM SOAP", and a household sponge were used to clean spatulas, stainless steel scoops, capsule machine parts, and a glass mortar and pestle used in production of "PENTOSAN POLYSULFATE SODIUM 150 MG DR CAPSULE", lot 07122022@(b), at your firm on July 12, 2022. Reusable glassware and utensils are utilized in the production of all non-sterile products such as, but not limited to, Pentosan PolySulfate capsules and Pyrimethamine-Leucovorin capsules.

B. There is no assurance that your cleaning process removes product and cleaning agent residue from your reusable glassware and utensils used in sterile production areas. Your support technician (b) (6) stated on July 12, 2022, that no measurements are used to create the diluted solution of "(b) (4) " detergent, which is utilized, with a household sponge, to clean all reusable parts for sterile production, and then rinsed with a (b) (4) mixture. (b) (6) stated (b) (6) prepares the detergent solution approximately (b) (4) and has prepared it without measurements for approximately two years. Per the detergent bottle directions, "(b) (4) . All sizes of graduated cylinders undergo (b) (4) washing and are not autoclaved prior to use in production operations. Graduated cylinders are utilized in the production of all your sterile products such as ophthalmic drops and injectable solutions. For example, a graduated cylinder was used in the production of "TIMOLOL - BRIMONIDINE - DORZOLAMIDE P-F OPTH (0.5/0.15/2) % SOLUTION" ophthalmic drops, lot 07122022@(b)(4

OBSERVATION 8

Your firm released drug product in which the strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

Specifically, hard gel capsules used during the production of (b) (4) "PENTOSAN POLYSULFATE SODIUM 150 MG DR CAPSULE", lot # 07122022@(b) (4) were at different heights when loaded into the capsule machine, and subsequently filled to different heights with the drug mixture. Approximately 26 out of (b) (4) capsules were filled to a noticeably lower height of (b) (4) volume than the others. Your PIC explained that (b) (4) fill volume directly correlates with drug product potency.

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OBSERVATION 9

ISO 5 classified areas were not certified under dynamic conditions.

Specifically, unidirectional airflow was not verified under dynamic operational conditions representative of your typical aseptic processing practices. Air visualization studies ("smoke studies") performed in two ISO 5 classified laminar airflow hoods (LAFH) and one ISO 5 classified biological safety cabinet (BSC), conducted on February 4, 2022, did not demonstrate unidirectional airflow, for example, around equipment and components, such as vials and bottles, observed during sterile production operations on July 12 and 29, 2022. Also, equipment and materials are placed too close to the respective HEPA grate or air intake openings at the back of the hood's work surface, which compromises unidirectional airflow.

In recording "LFH(b) (4) DYNAMIC SMOKE STUDY", conducted in (b) (4) airflow NJ-LAFH(b) (4) smoke is seen flowing upward and in a back current (time (b) (4)), creating non-laminar airflow in the critical zone including immediately behind and to the right of the (b) (4) filling station. Furthermore, unidirectional airflow was not demonstrated around the (b) (4) (b) (4) filling machine and a (b) (4) bottle observed during sterile production operations on July 12, 2022. This hood is used for the production of most ophthalmic products.

In recording "LFH(b) (4) DYNAMIC SMOKE STUDY", conducted in (b) (4) airflow NJ-LAFH(b) (4), unidirectional airflow was not demonstrated with "smoke" around the repeater pump and a (b) (4) bottle observed during sterile production operations on July 29, 2022. This hood is used for the production of all injectable products and one ophthalmic product.

In recording "BSC(b) (4) DYNAMIC SMOKE STUDY" and the two aforementioned LAFH smoke studies, unidirectional airflow is not demonstrated at all operational areas of each respective hood, including the full perimeter closest to the technicians, nor the airflow pattern upon contact with respective protective shielding (b) (4). The BSC is used for the production of cyclosporine-containing ophthalmic products.

***DATES OF INSPECTION**

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7/11/2022(Mon), 7/12/2022(Tue), 7/13/2022(Wed), 7/14/2022(Thu), 7/18/2022(Mon), 7/19/2022(Tue), 7/20/2022(Wed), 7/27/2022(Wed), 7/28/2022(Thu), 7/29/2022(Fri), 8/05/2022(Fri)

X Tekalign Wondimu
Investigator
Signed By: Tekalign Wondimu -S
Date Signed: 08-05-2022 17:06:29

X Amy N Chen
Investigator
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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."