DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE Suite 210 Bothell, WA 98021 (425)302-0340 Fax:(425)302-0404	10/16/2024-10/25/2024* FEI NUMBER 3014549846

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Amy A. Frost, Pharmacist- In- Charge

FIRM NAME	STREET ADDRESS
OSRX Inc.	1120 Kensington Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Missoula, MT 59801-5619	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 I OBSERVED:

OBSERVATION 1

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

Specifically,

A. Your firm's personal media fill is deficient in that aseptic operators only aseptically fill (b) (4) containers units, (b) (4), to fully qualify their sterile operators, under procedure, SOP-CC-0003, *Personnel Media Fill Qualification*. For example, to successfully qualify operator, (b) (6), (b) (7) (C) to produce sterile drug product in your cleanroom only (b) (4) units were filled aseptically, taking a total of (b) (4) to manufacture. This is not an adequate assessment of an operators aseptic technique when manufacturing a maximum batch size of (b) (4) units that takes (b) (4) to complete.

B. Your firm failed to incubate all integral units of the media fill performed under protocol VALRPT-001. In Cleanroom Suite 100, the following units were filled in ISO 5 BSC and then removed for (b) (4) testing and production loss reasons. All units removed were not incubated with documented justification:

Droptainers:

Lots	Filled Units	Total Removed	Incubated Units

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EMPLOYEE(S) SIGNATURE
Jazmine N Brown, Investigator

X Jazmine N Brown Investigator Signed By: Jazmine N. Brown -S Date Signed: 10-25-2024 20:06:02

DATE ISSUED
10/25/2024

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(b) (4)	8	(b) (4)
	8	
	23	
	19	
	69	
	16	

Vials:

Lots	Filled Units	Total Removed	Incubated Units
(b) (4)		11	(b) (4)
		23	
		15	

C. There is no gowning qualification program at your facility to enter into the Cleanroom Suite 100, room#(b) (4) (ISO 7) and room#(b) (4) (ISO 7), from the gowning in airlock (room #(b) (4)), to ensure sterile gowning is donned without contamination.

D. Your smoke study, performed on March 29, 2024, was not conducted under dynamic conditions

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to simulate aseptic processing behavior of the sterile drug production that includes (b) (4) employees working inside of the ISO 5 (b) (4) Biosafety Cabinet (BSC) simultaneously to perform check weighing, filling, and capping activities.

OBSERVATION 2

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 failed to thoroughly investigation quality events that had environmental monitoring recoveries that exceeded specification limits without adequate corrective actions, scientific justification, and impact assessment documented. For example,

i. QA-2024-0048 was initiated due to 1 cfu recovery of *Staphylococcus epidermidis* on an ISO 5 active viable air sample plate that was performed during the production of Brimonidine tartrate/ dorzolamide 1%2%, Lot:(b) (4), BUD: 23July2024. The batch was released without the proper batch impact assessment, corrective actions, and scientific rationale applied to the event prior to releasing and distributing the drug product to market.

ii. QA-2024-0071 was initiated due several environmental recoveries in Cleanroom Suite 100, but there was 1 cfu recovery of *Staphylococcus lentus* of an ISO 5 active viable air sample plate that was performed during the production of Prednisolone Phosphate Moxifloxacin Bromide 1%0.5%0.075%, Lot (b) (4) Expiry 25Nov2024. The batch was released without the proper batch impact assessment, corrective actions, and scientific rationale applied to the event prior to releasing and distributing the drug product to market.

B) Your firm failed to investigate visual inspection failures that exceeded the specification limits

without adequate documentation, impact assessment, and corrective actions in place prior to releasing and distributing the drug product, in example, Prednisolone Phosphate 1%/ Moxifloxacin 0.5% Ophthalmic solution 5ml, Lot: (b) (4), BUD: 10Dec2024.

OBSERVATION 3

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

Specifically,

A) There are no ISO 5 viable surface samples taken during the earlier lots being manufactured in clean room# (b) (4) (ISO7) and clean room# (b) (4) (ISO7) on each day of aseptic production. For example, Atropine 0.01%, Sulfate Monohydrate, Lot: (b) (4), BUD 14Apr25, and Prednisolone Phosphate 1% / Moxifloxacin 0.5% / Bromfenac 0.075%, Lot: (b) (4), BUD:15Apr25, both were manufactured on (b) (4) and did not have an associated surface sample of the ISO 5 Biosafety Cabinet performed at the end of each batch operation.

B) Your firm's procedure, SOP-CC-0026, *Routine Environmental Monitoring Cleanroom 100*, lists the action level for viable surface sample at (b) (4) colonies per forming units per sampling device, which is not appropriate for an ISO 5 environment.

C) On 10/17/2024, I observed a fingertip sample being performed on an operator during end of production batch, Atropine Sulfate Monohydrate 0.05% Ophthalmic Solution 3.5ml, Lot: (b) (4), BUD:15APR2025, and it appears that the operator does not fully engage their fingers onto the agar with a (b) (4) technique.

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OBSERVATION 4

Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.

Specifically, your firm performed an early release of drug product, Brimonidine Tartrate 0.1%, Dorzolamide 2%, 2ml Ophthalmic Solution, Lot: (b) (4), BUD:26May2024, without the sterility testing being completed by your third party laboratory as documented in QE-2024-0032.

OBSERVATION 5

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

Specifically, your firm's procedure SOP-INSP-0001, entitled, *Visual Inspection of Sterile Compounded Topical Ophthalmic Preparations,* fails to implement adequate specifications to prevent significant product quality issues from occurring, as follows:

A. There is no sound visual inspection program that contains a qualified visual inspection sample defect kit used to train visual inspectors to inspect topical ophthalmic solutions manufactured in opaque droptainers.

B. You does not examine 100% of units produced for topical ophthalmic drug products. Instead, you only perform an examination of (b) (4) opaque topical droptainers as a form of Acceptable Quality Limit (AQL) inspection without scientific rationale. Your firm only performs an 100% inspection of the rejected AQL inspection for that failed defect category with a (b) (4) AQL using the same accept/ reject limits.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
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C. There is no total reject rate for an accumulated total of rejects per inspection. Your firm uses an accept/ reject rate per defect type and not as a total for the critical/ major/ minor classification categories.

D. Furthermore, during the AQL inspection, (b) (4) opaques topical droptainers are sampled (b) (4) and sampling is not representative of the entire lot ((b) (4) and (b) (4) of fill).

OBSERVATION 6

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

Specifically, your containers do not include a label that includes the following information:

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

B. Directions for use, including, as appropriate, dosage and administration.

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

i. Prednisolone Phosphate 1% Moxifloxacin 0.5% Bromfenac 0.075% 8mL Sterile Ophthalmic Solution

ii. Atropine Sulfate 0.05% 3.5mL Sterile Ophthalmic Solution

iii. Timolol 0.5% Brimonidine Tartrate 0.1% Dorzolamide 2% 5mL Sterile Ophthalmic Solution

iv. Moxifloxacin 0.5% Bromfenac 0.075% 5mL Sterile Ophthalmic Solution

v. Prednisolone Phosphate 1% Moxifloxacin 0.5% 5mL Sterile Ophthalmic Solution

vi. Prednisolone Phosphate 1% Moxifloxacin 0.5% Bromfenac 0.075% 8mL Sterile Ophthalmic Solution

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vii. Prednisolone Phosphate 1% Moxifloxacin 0.5% Bromfenac 0.075% 5mL Sterile Ophthalmic Solution
viii. Prednisolone Phosphate 1% Bromfenac 0.075% 5mL Sterile Ophthalmic Solution
ix. Atropine Sulfate 0.01% 3.5mL Sterile Ophthalmic Solution
x. Atropine Sulfate 0.025% 3.5mL Sterile Ophthalmic Solution
xi. Atropine Sulfate 0.05% 3.5mL Sterile Ophthalmic Solution
xii. Timolol 0.5% Bimatoprost 0.01% 5mL Sterile Ophthalmic Solution
xiii. Timolol 0.5% Brimonidine Tartrate 0.1% Dorzolamide 2% 5mL Sterile Ophthalmic Solution
xiv. Timolol 0.5% Brimonidine Tartrate 0.1% Dorzolamide 2% Bimatoprost 0.01% 5mL Sterile Ophthalmic Solution
xv. Tropicamide 1% Phenylephrine HCl 2.5% 2mL Sterile Ophthalmic Solution
xvi. Brimonidine Tartrate 0.1% Dorzolamide 2% 2mL Sterile Ophthalmic Solution
xvii. Dexamethasone Phosphate 0.1% Moxifloxacin HCl 0.5% 1mL Sterile Ophthalmic Solution PF

***DATES OF INSPECTION**

10/16/2024(Wed), 10/17/2024(Thu), 10/18/2024(Fri), 10/21/2024(Mon), 10/22/2024(Tue), 10/23/2024(Wed), 10/24/2024(Thu), 10/25/2024(Fri)

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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."