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	11/3/2025-11/14/2025* FEI NUMBER 3014549846

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Amy A. Frost, Chief Pharmacy Officer, PIC

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 WE OBSERVED:

PRODUCTION

OBSERVATION 1

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

Specifically,

A. Active viable air and non-viable air sampling is not representative of the aseptic filling process. Active viable air is sampled for (b)(4) during production of each lot (SOP-CC-0014 Technical Guide Viable Air Sample, page 4 of 12, section 9.6). Procedures do not state when during production it is done. The non-viable air sampler is also ran for (b)(4). Filling time during routine production can range from (b)(4).

B. Your firm's personal media fills (to qualify personnel) and aseptic process simulations (to qualify the process) do not closely simulate routine production operations. During routine production, personnel can:

- Fill or add tips to (b)(4) droptainers of Atropine Sulfate Monohydrate 0.025% Ophthalmic Solution 3.5 ml, Lot 206446, BUD: 29JUN2026

or

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Rowena S Nguyen, Investigator Thuy Tram L Nguyen, Investigator	X Rowena S Nguyen Investigator Signed By: Rowena S. Nguyen -S Date Signed: 11-14-2025 13:04:51	11/14/2025

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	11/3/2025-11/14/2025* FEI NUMBER 3014549846

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Amy A. Frost, Chief Pharmacy Officer, PIC	
FIRM NAME OSRX Inc.	STREET ADDRESS 1120 Kensington Ave
CITY, STATE, ZIP CODE, COUNTRY Missoula, MT 59801-5619	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

- Fill or add septums (stoppers) to (b)(4) vials of Dexamethasone Phosphate 0.1% + Moxifloxacin Hydrochloride 0.5% Ophthalmic Injection 1 ml, Lot 206594, BUD: 14APR2026.

  However, during personnel media fills and aseptic process simulations, the operator will sometimes fill less. For example:

i. As part of SOP-CC-0025 Personal Media Qualification, Version 3, Effective Date: 21FEB2025, personnel perform (b) (4) passing personal media fills on (b) (4). Each personal media fill requires them to do line set up and fill no less than (b) (4) droptainers. They subsequently add the tips/caps within the same media fill. There are no personal media fills performed with vials.

ii. During aseptic process simulations used for qualifying the process for:

- Droptainers (Report ID: MFR - 25 – 0002), production personnel (b) (6), added (b)(4) tips/caps, but during routine production of Lot 206446, they added (b)(4) tips/caps on droptainers.
- Vials (Report ID: MFR-25-001), production personnel (b) (7) (C), added septums (stoppers) on (b)(4) vials, but during routine production of Lot 206594, they added (b)(4) septums (stoppers) on vials.

THIS IS A REPEAT OBSERVATION

C. Your firm's smoke studies (performed 25SEP2025) for production of drug products in droptainers is not adequate. For example:

i. At 19:47, the filler appears to be blocking first pass air of (b) (4) column filled, while beginning to fill the (b) (4) column.

ii. At 20:10, the filler turns the tray to fill the remaining (b) (4) columns. They start with the (b) (4) column then, fill the (b) (4) column last. SOP-FIL-0001 Filling Operation section 8.3.16 states to fill the (b) (4) column first, then the (b) (4) column.

iii. The amount of smoke used and the camera angle are not adequate to see the movement of smoke in critical areas:
   a. above open droptainers being filled
   b. above filled droptainers when they are adding tips/caps

THIS IS A REPEAT OBSERVATION

D. Disinfectant efficacy studies have not been performed for the disinfectant (b) (4) (b) (4) used to wipe (b) (4) and disposables that are wiped down in the ISO (b) (4) and ISO (b) (4) cleanrooms.

QUALITY

OBSERVATION 2

Written records of investigations into unexplained discrepancies do not always include the conclusions and follow-up.

Specifically,

A. Your firm's complaint system is not adequate. Complaints regarding quality do not always lead to an investigation, investigations or outcomes are not always documented and investigations are not always adequate. For example:

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	11/3/2025-11/14/2025* FEI NUMBER 3014549846

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Amy A. Frost, Chief Pharmacy Officer, PIC

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

- On 24FEB2025, your pharmacist received a report ((b)(4)) from a patient regarding drug product Prednisolone Phosphate 1% + Moxifloxacin 0.5% + Bromfenac 0.075% Ophthalmic Solution 8ml, Lot 105095, BUD: 15JUN2025. The patient stated that the product caused a burning sensation in the eye for at least five minutes each time they used it (3 times total). This was not forwarded to quality assurance based on the pharmacist's discretion. No investigation was documented.

b. On 09JUL2025, your pharmacist received a report ((b)(4)) from a patient regarding drug product Prednisolone Phosphate 1% + Bromfenac 0.075% Ophthalmic Solution 5ml, Lot 205126, BUD: 10JAN2026. The patient stated that she found a very tiny floating thing (orangish/yellowish) after she used the eye drops. The medication incident form indicated that this report was forwarded to quality assurance, but quality assurance did not receive it.

c. Investigation of complaints is not adequate. The firm received the following complaints:

Quality Event #	Complaint	Date Reported	Name, active ingredients, strength	Package Size ml	Lot Number	Date Made	BUD	Qty Units
QE-2025-0083	eyelid swelling	15-Oct-25	Prednisolone Phosphate 1% + Moxifloxacin 0.5% + Bromfenac 0.075%	8	206063	8/21/2025	2/17/2026	(b)(4)
QE-2025-0075	eyelid swelling	13-Oct-25	Prednisolone Phosphate 1% + Moxifloxacin 0.5% + Bromfenac 0.075%	5	206033	8/15/2025	2/11/2026	(b)(4)
QE-2025-0075	eyelid swelling	13-Oct-25	Prednisolone Phosphate 1% + Moxifloxacin 0.5% + Bromfenac 0.075%	5	205980	8/8/2025	2/4/2026	(b)(4)

A third-party lab performed assay testing on sample retains for lots 206063, 206033 and

205980. In addition, pH and appearance were tested. However, there was no documentation of sterility testing performed.

B. Out Of Specification (OOS) investigations do not always identify a root cause, when they do not move forward to a phase 2 investigation. For example:

On 11SEP2025, OOS-2025-008 was initiated for a low assay result of (b) (4) (b) (4) in drug product Prednisolone Phosphate 1% + Bromfenac 0.075% Ophthalmic Solution 5 ml, item code 5055, Lot 206150, BUD: 26MAY2026. Retesting was performed, but no root cause was identified. This product was released for dispensing on 05NOV2025.

LABORATORY

OBSERVATION 3

The reproducibility of test methods have not been established.

Specifically,

Your firm uses (b)(4), a (b) (4) test method, for sterility testing release of finished drugs. However, there is no established procedure to identify organisms to the species in the event of a sterility failure.

OBSERVATION 4

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically,

Audit trail review of your instruments HPLC-(b) (4) and HPLC-(b) (4) is not performed for each analytical

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	11/3/2025-11/14/2025*
	FEI NUMBER 3014549846

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Amy A. Frost, Chief Pharmacy Officer, PIC

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

record prior to release of each drug product. HPLC-(b)(4) is used to test assay for the analytes Pred-Moxi-Brom (s) and Atropine(s). HPLC-(b)(4) is used to test (b)(4) and for research and development. For example, Atropine Sulfate Monohydrate 0.025% Ophthalmic Solution 3.5 ml, Lot 206446, BUD: 29JUN2026 was tested on HPLC-(b)(4) for Atropine(s) and released without audit trail review.

***DATES OF INSPECTION**

11/03/2025(Mon), 11/04/2025(Tue), 11/05/2025(Wed), 11/06/2025(Thu), 11/07/2025(Fri), 11/10/2025(Mon), 11/11/2025(Tue), 11/12/2025(Wed), 11/13/2025(Thu), 11/14/2025(Fri)

X Thuy Tram L Nguyen
Investigator
Signed By: Thuy Tram Nguyen -S
Date Signed: 11-14-2025 13:05:36

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Rowena S Nguyen, Investigator
Thuy Tram L Nguyen, Investigator

X Rowena S Nguyen
Investigator
Signed By: Rowena S. Nguyen -S
Date Signed: 11-14-2025 13:04:51

DATE ISSUED
11/14/2025

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."