DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Seattle District Office 22215 26th Ave. SE, Suite 210, Bothell, WA 98021 (425) 302-0340 Industry Information: www.fda.gov/oc/industry	09/15/21 to 09/23/21* FEI NUMBER 3014549846

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dr. Amy K. Frost, Pharmacist-in-Charge

FIRM NAME	STREET ADDRESS
OSRX, Inc. ~~dba Pinnacle Compounding~~ SMK 9/23/21	1120 Kensington Ave., Unit E
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Missoula, MT 59801	Producer of 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 (I) (WE) OBSERVED:

OBSERVATION 1

Your firm's current laminar airflow studies (smoke studies) of the ISO 5 (b) (4) Laminar Airflow Workstation were not performed under conditions showing aseptic operations that are representative of your current compounding practices nor did they emulate all critical unit operations and interventions used during compounding of your sterile drug products. Specifically,

Smoke studies conducted by your firm in May of 2021 were not conducted under dynamic conditions that fully simulate the normal operating conditions of the sterile drug production.

1) You did not simulate the entire filling process, including the priming of the pump used to fill the vials with the compounded drug product.

2) You also did not simulate the practice of two operators working together in your ISO 5 Laminar Air Flow Hood during filling, capping and sealing operations.

*DATES OF INSPECTION
09/15/2021 (Wed), 09/16/2021 (Thu), 09/17/2021 (Fri), 09/20/2021 (Mon), 09/21/2021 (Tue), 09/22/2021 (Wed), 09/23/2021 (Thu)

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Sangeeta M. Khurana	Sangeeta M. Khurana Investigator Kenneth O. Gee Investigator	09/23/2021

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 judgement, 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."