DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612 (949) 608-2900 Fax: (949) 608-4417 Industry Information: www fda.gov/oc/industry	8/4/2022 - 812/2022* FEI NUMBER 3011893599

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Nayan Patel, CEO

FIRM NAME	STREET ADDRESS
Auro Pharmacies, Inc.	520 W La Habra Blvd
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
La Habra, CA 90631	Compounding Pharmacy

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
You produced hazardous drugs without providing adequate containment or cleaning of and work surfaces to prevent cross-contamination.

Specifically, an accumulation of what appeared to be white powder was observed in areas on your (b) (4) hoods. On 8/4/2022, the area under the HEPA filters and the bolts on the front shield of two hoods had the apparent powder accumulation. The hoods are used for hazardous drug encapsulation during compounding operations and identified as (b) (4) and (b) (4). (b) (4) hazardous (including Progesterone, Estradiol, and Anastrozole) lots were manufactured on 8/4/2022.

OBSERVATION 2
Non-microbial contamination was observed in your production area.

Specifically, an accumulation of what appeared to be white powder was observed in areas on your (b) (4) hoods. On 8/4/2022, the area under the HEPA filters and the bolts on the front shield of two hoods had the apparent powder accumulation. The hoods are used for non-hazardous drug encapsulation during compounding operations and identified as (b) (4) and (b) (4). (b) (4) non-hazardous (including Pregnenolone/DHEA, T3, T4/T3, and Naltrexone) capsule lots were manufactured on 8/4/2022.

*Dates of Inspection
8/4/2022, 8/5/2022, 8/8/2022, 8/10/2022, and 8/12/2022

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Bryan Galvez -S Digitally signed by Bryan Galvez -S Date: 2022.08.12 13:57:10 -07'00'	Bryan Galvez, CSO	8/12/2022

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."