DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
11155 Dolfield Boulevard, Suite 117 Owings Mills, MD 21117 (410)779-5455 Fax:(410)779-5707 ORAPHARM1_RESPONSES@fda.hhs.gov	8/26/2024-9/6/2024* FEI NUMBER 3020928491

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Adedayo Akinbi, Founder and Chief Executive Officer

FIRM NAME	STREET ADDRESS
Annovex Pharma, Inc.	7403 Lockport Pl Ste C-D
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Lorton, VA 22079-1569	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:

OBSERVATION 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic process.

Specifically, your firm's media fill program is inadequate as it does not provide an assurance that your staff can manufacture drug product under aseptic conditions. The following deficiencies were identified:

A-You did not incubate all integral units during the (b) (4) incubation period for *Media Fills* performed at your site. For example, during the *Media Fill* performed on 07/29/2024, (b) (4) syringes were filled, but only (b) (4) randomly selected syringes incubated. Furthermore, there is no scientific justification provided for not incubating all (b) (4) integral units.

B-You did not ensure that the purchased media powder used for *Media Fill* studies is growth promoted and suitable for its intended use, prior to use. For example, on 01/10/2024, during an Aseptic Process Simulation, the in-house prepared media (lot# (b) (4)) was not inoculated with the USP-recommended microorganism. This step is necessary to confirm that the media can promote microbial growth effectively.

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.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Tekalign Wondimu, Investigator Kara J Wright, Investigator Yaharn Su, Investigator	X Tekalign Wondimu Investigator Signed By: Tekalign Wondimu -S Date Signed: 09-06-2024 09:30:54	9/6/2024

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Specifically,

A- Microbial growth was observed in 100 syringes (units (b) (4)) for the media fill performed on 01/04/2024. On 01/05/2024, your quality unit discarded all 100 of the (b) (4) syringes that showed microbial growth without providing scientific justification. Additionally, surface and gloved fingertip samples obtained during this process were not incubated beyond day (b) (4) You did not make an attempt to identify the organism(s) in the turbid units or assess the impact on blended drug products produced since the last successful *Media Fill*.

B- You did not initiate an investigation or deviation for the HEPA filter leak test failure in the classified Buffer Room (b) (4) (ISO 7) observed during the Dec 2023 recertification. In addition, you do not have a procedure in place to evaluate HEPA filter failures or patches nor product impact on items that are potentially affected.

OBSERVATION 3

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

Specifically, unidirectional airflow was not verified under dynamic conditions representative of your typical production process. Smoke studies conducted in July 2024 in your ISO 5 laminar air flow hoods did not show manipulations or conditions performed (Sterile connection to bulk solution/bag, initial setup of repeater pump in use) that would be representative of the dynamic process used in actual production processes.

OBSERVATION 4

Written procedures are lacking which describe in sufficient detail the storage of components, drug product containers and closures.

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Specifically, there is no temperature monitoring in the warehouse where raw material and blended drugs products are stored. For example, there are (b) (4) units of Phenylephrine HCl 25 mg in 0.9% Sodium Chloride 250 mL Bag, lot# LBN 24.08.00000014 (with storage temperature specifications of (b) (4) to (b) (4) stored in the blended product storage area.

OBSERVATION 5

Records associated with drug product production and control and within the retention period for such records, were not made readily available for authorized inspection.

Specifically, *Media Fill* records from 06/27/2023, 6/28/2023 and 7/10/2023 were unavailable and could not be retrieved for review.

OBSERVATION 6

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

Specifically, the following information is not found on your drug product labels:

A list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient.

- Examples of your drug product labels that do not contain this information:
  - Lorazepam 0.25 mg/0.125 ml and 0.5 mg/0.25 ml oral concentrates;
  - Morphine Sulfate 5 mg/0.25 ml oral concentrate; and
  - Oxycodone HCl 10 mg/0.5 ml, 5 mg/0.25 ml, 2.5 mg/0.125 ml oral solutions.

OBSERVATION 7

Your outsourcing facility did not submit a report to FDA identifying the drugs compounded during the previous six month period.

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	Tekalign Wondimu, Investigator Kara J Wright, Investigator Yaharn Su, Investigator	X Tekalign Wondimu Investigator Signed By: Tekalign Wondimu -S Date Signed: 09-06-2024 09:30:54	9/6/2024

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Specifically, the following products were compounded and not identified on your product report dated June 2024.

- Heparin 4 units/mL in 1000 ml
- Phenylephrine 100 mcg/ml in 10 ml syringes
- Phenylephrine HCl 25 mg in 250 ml

***DATES OF INSPECTION**
8/26/2024(Mon), 8/27/2024(Tue), 8/28/2024(Wed), 8/29/2024(Thu), 8/30/2024(Fri), 9/03/2024(Tue), 9/06/2024(Fri)

X Yaharn Su
Investigator
Signed By: 2004003466
Date Signed: 09-06-2024 09:31:37

X Kara J Wright
Investigator
Signed By: 2004338119
Date Signed: 09-06-2024 09:32:00

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Tekalign Wondimu, Investigator Kara J Wright, Investigator Yaharn Su, Investigator	X Tekalign Wondimu Investigator Signed By: Tekalign Wondimu -S Date Signed: 09-06-2024 09:30:54	9/6/2024

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."