DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	3/30/2022-4/15/2022*
	FEI NUMBER 3021028639

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Joshua Kent Miles, Owner and Pharmacist-In-Charge	
FIRM NAME Lynn Oaks Compounding Pharmacy	STREET ADDRESS 2220 Lynn Rd Ste 101
CITY, STATE, ZIP CODE, COUNTRY Thousand Oaks, CA 91360-8018	TYPE ESTABLISHMENT INSPECTED Producer of Non 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 WE OBSERVED:

OBSERVATION 1

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

Specifically,

Your firm routinely produces hazardous/highly potent non-sterile drug products (containing digoxin, chlorambucil, tacrolimus, zonisamide, tretinoin or hormones) without providing adequate containment, cleaning of utensils and work surfaces to prevent cross-contamination. During the period from 1/1/2022 to 3/31/2022, your firm produced (b) (4) drug products with hazardous /highly potent drugs accounting for approximately (b) (4) % of all drug products.

A. On 3/30/2022, we observed your non-sterile technician spill powders onto the surfaces of the Biological Safety Cabinet ((b) (4)) and the balance ((b) (4) inside the cabinet during processing of Zonisamide, 20 mg/ml, Rx(b) (6) a hazardous drug. The technician used (b) (4) a commercially available non-pharmaceutical grade dish detergent followed by (b) (4) (b) (4) to wipe down of surfaces of the cabinet and equipment for cleaning and sanitizing before the start of Fenbendazole 10 mg/ml, Rx (b) (6) and stated it was a standard practice for cleaning and sanitizing in-between production. however, there is no assurance that these cleaning agents are appropriate to inactivate, decontaminate and/or remove the potent/hazardous drug substances from the production area.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Taichun Qin, Investigator James B Arnett, Investigator	DATE ISSUED 4/15/2022

Taichun Qin
Investigator
Signed By: 2001324946
Date Signed: 04-15-2022
11:11:03

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
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B. On 3/30/2022, we observed your technician did not clean interior surfaces of sliding glass doors of the balance in the biological safety cabinet and the counter where in-process products in liquid or semisolid form were further processed into finished products after completing production of Zonisamide, 20 mg/ml, Rx(b) (6) and before the start of Fenbendazole 10 mg/ml, Rx (b) (6) Also, a beaker and utensils containing residues of Zonisamide, 20 mg/ml were left on the counter.

C. We observed a plastic basket near the sink in the anteroom used to hold mortar, beaker and utensils after cleaning looked dirty with unknown white stains on the surfaces on 3/30/2022 and 4/5/2022.

OBSERVATION 2

You used a non-pharmaceutical grade component in the formulation of a drug product.

Specifically,

A) Analytical Standard Digoxin, Batch Number (b) (4) purchased from (b) (4) was used in producing Home Hospice EOL SUS as the active pharmaceutical ingredient. During the period of January to March, 2022, your firm produced this drug for patient-specific prescriptions for the following: Rx(b) (6) , Rx(b) (6) Rx(b) (6) and Rx(b) (6) .

B) (b) (4) (b) (4) was used in producing all water-containing drug products. During the period of January to March, 2022, you produced Pantoprazole 2 mg/ml GTUBE Suspension for 3 patient-specific prescriptions (Rx (b) (6) , Rx (b) (6) , and Rx (b) (6)) and Tetracaine 6% Topical Solution, Rx(b) (6) for office use using filtered water.

OBSERVATION 3

Vermin was observed in your production area.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Taichun Qin, Investigator James B Arnett, Investigator	Taichun Qin Investigator Signed By: 2001234645 Date Signed: 04-15-2022 11:17:28 X JBA	4/15/2022

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19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	3/30/2022-4/15/2022* FEI NUMBER 3021028639

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Specifically,

We observed that a living insect was crawling on the exterior surface of the biological safety cabinet on the left side on 3/30/2022 in the "compounding room". The sliding door entry to the "compounding room" is always opened to the outside retail pharmacy area when producing non-hazardous drugs, and is closed only when producing hazardous drugs. For example, the door in the "compounding room" was opened while your non-sterile technician produced DICL/KETO/LIDO 2.5/10/7.5 Cream on 4/1/2022 and Clarithromycin 375 mg , Rx (b) (6) Capsule on 4/5/2022.

OBSERVATION 4

Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.

Specifically,

You did not test non-sterile topical preparations for presence of objectionable microorganisms prior to distribution. For example, your firm produced drug products for office use between January and March, 2022 for the following:

- Tetracaine 6% Topical Solution
- Profound Easy Oral Gel
- Skin Renew Medical, Benzo/Lido/Tetra, 6/6/4% Cream
- Benzocaine 20% SUSP
- Benzo/Lido/Tetra, 20/5/10% Ointment

None of these drug products were tested for presence of objectionable microorganisms.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Taichun Qin, Investigator James B Arnett, Investigator X Taichun Qin Investigator Signed By: 2001324646 Date Signed: 04-15-2022 11:17:20 EDT	4/15/2022

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OBSERVATION 5

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications and identity and strength of each active ingredient prior to release.

Specifically,

Your firm failed to conduct appropriate tests to determine the identity and strength of each active ingredient in non-sterile drug products produced for offices use prior to release and distribution. For example, your firm produced drug products for office use between January and March, 2022 for the following:

- Tetracaine 6% Topical Solution
- Profound Easy Oral Gel
- Skin Renew Medical, Benzo/Lido/Tetra, 6/6/4% Cream
- Benzocaine 20% SUSP
- Benzo/Lido/Tetra, 20/5/10% Ointment

You did not conduct assay or other appropriate tests for these drugs.

OBSERVATION 6

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Taichun Qin, Investigator James B Arnett, Investigator Taichun Qin Investigator Signed By: 2001324640 Date Signed: 04-15-2022 11:17:26 EDT X	4/15/2022

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Your firm assigned an expiration date for a drug product produced for office use with no stability study conducted for the product. For example, you assigned a 12-month expiration date for Benzo/Lido/Tetra, 6/6/4% Cream and Profound Easy Oral Gel produced at your firm for office use with no stability data to support the expiration date.

OBSERVATION 7

The calibration of instruments is not done at suitable intervals with provisions for remedial action in the event accuracy and/or precision limits are not met.

Specifically,

Your firm calibrated the balance inside the biological safety cabinet using a standard weight (b)(4) g according to instructions on the Form of 2022 (b) (4) Calibration of Balance; however, your calibration did not cover the range of weight of active pharmaceutical ingredients recorded in the logged formula worksheets. For example, your firm used Tetracaine 4.8 g, Prilocaine 6g, Lidocaine HCL 6g, and Phenylephrine HCL 2.4 g to produce Profound Easy Oral Gel, Rx (b) (6) on 2/23/2022, and tetracaine 14.4 g to produce tetracaine 6% solution, Rx (b) (6) on 2/24/2022. This balance has not been calibrated.

***DATES OF INSPECTION**

3/30/2022(Wed), 3/31/2022(Thu), 4/01/2022(Fri), 4/05/2022(Tue), 4/15/2022(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Taichun Qin, Investigator James B Arnett, Investigator	X Taichun Qin Investigator Signed By: 2001224546 Date Signed: 04-15-2022 11:17:38	4/15/2022

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 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."