DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	9/4/2018-9/14/2018* FEI NUMBER 3002946561

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
John T. Sorci, Pharmacist

FIRM NAME	STREET ADDRESS
White House Pharmacy Inc. dba San Jose Compounding Pharmacy	2453 Forest Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Jose, CA 95128-1505	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 I OBSERVED:

OBSERVATION 1

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

a) Specifically, your firm produced beta-lactam products (b) (4) times on the same day and in the same room (Lab Room) as non-beta lactam products. Your firm produces beta-lactam products on a shared table within 2 feet distance of non-beta lactam products.

This table shows the date made, beta-lactam and quantity of non-beta lactam product produced.

Date Made	Beta-Lactam Produced in Lab Room	Number of Non-Beta Lactam Products Produced in the Lab Room on the Same Day
12/16/2016	Amoxicillin/Clavulanate 50MG/12.5MG/ML	(b) (4)
1/3/2017	Amoxicillin 350 MG Suppository	
5/18/2017	Amoxicillin 100 MG Chew	
7/5/2017	Amoxicillin 100 MG Chew	

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EMPLOYEE(S) SIGNATURE
Kristin M Abaonza, Investigator

X Kristin M Abaonza
Investigator
Signed By: Kristin M. Abaonza -S
Date Signed: 09-14-2018 16:08:27

DATE ISSUED
9/14/2018

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7/11/2017	Amoxicillin 500MG/ML Suspension	(b) (4)
8/4/2017	Amoxicillin 500MG/ML Suspension	
8/31/2017	Amoxicillin 500MG/ML Suspension	
10/13/2017	Penicillamine 125 MG Capsule	
12/4/2017	Ceftazidime 500 MG Suppository	
12/5/2017	Ceftazidime 500 MG Suppository	
12/29/2017	Penicillamine 125 MG Capsule	
3/6/2018	Penicillamine 125 MG Capsule	
4/9/2018	Penicillamine 125 MG Capsule	
5/17/2018	Ceftazidime 500 MG Suppository	
5/23/2018	Amoxicillin 40MG/ML Suspension/Amoxicillin 42MG/ML Suspension	
5/29/2018	Penicillamine 125 MG Capsule	
7/5/2018	Ceftazidime 500 MG Suppository/Amoxicillin 100MG/ML Suspension	
7/8/2018	Penicillamine 125 MG Capsule	
8/6/2018	Ceftazidime 500 MG Suppository	
8/14/2018	Penicillamine 125 MG Capsule	
9/4/2018	Penicillamine 125 MG Capsule	

b) Your firm cleans work surfaces (in between products) in your Lab Room with (b) (4) (b) (4) which is not effective in deactivating beta-lactams.

c) On 9/4/2018, your firm used (b) (4) dish soap and water to clean dirty equipment used in the production of Penicillamine 125 MG capsules (Lot# 09042018#9428-02@8), which is not effective in deactivating beta-lactams.

OBSERVATION 2

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

Specifically, your firm produced (b) (4) prescriptions of Hydrocodone Bitartrate 10 MG capsules and (b) (4) prescriptions of Fentanyl Sorbitol Base (Veggie) 500 MCG Lollipops from 10/31/2016-9/6/2018.

a) Your firm produced the Hydrocodone Bitartrate 10 MG capsules and the Fentanyl Sorbitol Base (Veggie) 500 MCG Lollipops in your Lab Room, while other patient specific prescriptions were being produced, on a shared table with limited space. Your pharmacy technician stated up to (b) (4) different products can be produced at one time.

b) Your firm cleans work surfaces with (b) (4), and dirty equipment (used to produce highly potent products) with (b) (4) and (b) (4) (b) (4) which is not effective in removing highly potent residues.

OBSERVATION 3

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

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Specifically, you produce patient specific prescriptions from hormonal Active Pharmaceutical Ingredients (APIs), such as Testosterone and Progesterone in your Hazardous Room at the same time as other hazardous products. Between 6/1/2018 and 9/4/2018, your firm produced (b) (4) progesterone prescriptions.

a) Your written procedure entitled, "Cleaning and Maintenance of the Non-Sterile Compounding Area" SOP Number: 3.050 states in Section 10.0, "Approved cleaning solutions are (b) (4) (b) (4) or (b) (4) . Approved decontaminating solution is (b) (4) ." The above listed cleaning and decontaminating solutions used to clean work surfaces and dirty equipment in your Hazardous Room and are not effective in deactivating hazardous drugs.

OBSERVATION 4

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

On 8/23/2018, your firm produced (b) (4) capsules of Progesterone 100 MG capsules with a non-pharmaceutical grade component, namely food grade "(b) (4) " (Lot#(b) (4) Expiration Date: 8/8/2019) manufactured by (b) (4)

a) You stated that your firm ran out of (b) (4) and purchased food grade (b) (4) from the grocery store to produce the Progesterone 100 MG capsules.

***DATES OF INSPECTION**

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Kristin M Abaonza, Investigator	X Kristin M Abaonza Investigator Signed By: Kristin M. Abaonza -S Date Signed: 09-14-2018 16:08:27	9/14/2018

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9/04/2018(Tue), 9/05/2018(Wed), 9/06/2018(Thu), 9/07/2018(Fri), 9/10/2018(Mon), 9/11/2018(Tue), 9/12/2018(Wed), 9/14/2018(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Kristin M Abaonza, Investigator	X Kristin M Abaonza Investigator Signed By: Kristin M. Abaonza -S Date Signed: 09-14-2018 16:08:27	DATE ISSUED 9/14/2018