

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax: (214) 253-5314	DATE(S) OF INSPECTION 2/19/2020-2/26/2020*
	FEI NUMBER 3015826783

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Robbie Lee Surratt Jr., Director of Pharmacy Operations

FIRM NAME Solaris Pharmacy, Inc.	STREET ADDRESS 1308 E Old Chico Rd
CITY, STATE, ZIP CODE, COUNTRY Decatur, TX 76234-3405	TYPE ESTABLISHMENT INSPECTED Producer of Non-Sterile Drugs

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

Cleaning agents used to disinfect, clean, sanitize equipment and/or production areas of non-sterile drug products are not suitable for use.

Specifically,

- a) On February 19, 2020, I observed the firm's non-sterile technician (b) (6) use (b) (4) to clean and disinfect the (b) (4) capsule instrument. The directions for use on the label states that it is "intended for use" on "non-food surfaces". However, your firm routinely produces capsules for oral use. Approximately, (b) (4) batches of drug product capsules were produced since November 1, 2019 for oral administration.
- b) On February 19, 2020, I observed your firm's non-sterile technician (b) (6) use expired sterile (b) (4) to clean and sanitize the (b) (4) capsule instrument and table in the non-sterile compounding room during the production of Budesonide Inhalation Capsules 320mcg, Lot #1951 with a Beyond Use Date of 08/19/20.

OBSERVATION #2

Non-pharmaceutical grade components are not used in the production of your non sterile drug products.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Patty P Kaewussdangkul, Investigator	Patty P Kaewussdangkul Investigator Signed by Patty P. Kaewussdangkul -S Date Signed 02-26-2020 14:08:22 X	DATE ISSUED 2/26/2020

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Your firm used commercially purchased (b) (4) to make (b) (4), a component that is used in your non-sterile compounded drugs for oral, topical and mucosal administration. There is no assurance that the store bought (b) (4) purchased is suitable for its intended use. For example, the following non sterile drug products for oral use were produced using (b) (4) that was made with store bought (b) (4) :

- a) Hydromorphone Oral Concentrate Lot #1362 with a Beyond Use Date (BUD) of 3/20/20 with (b) (4) Lot #1205.
- b) Morphine Oral Concentrate Lot #1363 with a BUD of 3/20/20 with (b) (4) Lot #1205.
- c) Atropine Oral Solution 1% Lot #1387 with a BUD of 3/23/20 with (b) (4) Lot #1332.

***DATES OF INSPECTION**

2/19/2020(Wed), 2/20/2020(Thu), 2/21/2020(Fri), 2/24/2020(Mon), 2/26/2020(Wed)

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