

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

DISTRICT ADDRESS AND PHONE NUMBER US Customhouse Rm900 200 Chestnut St Philadelphia, PA 19106 (215) 597-4390 Ext:4200 Fax: (215) 597-0875 ORAPHARM1_RESPONSES@fda.hhs.gov	DATE(S) OF INSPECTION 1/19/2022-2/3/2022*
	FEI NUMBER 3000214934

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Harry Lindenmuth , Site Director, Audubon-Pharma Services

FIRM NAME Almac Pharma Services LLC	STREET ADDRESS 2661 Audubon Rd
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CITY, STATE, ZIP CODE, COUNTRY Audubon, PA 19403-2413	TYPE ESTABLISHMENT INSPECTED Drug Packager and Labeler
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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

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically,

Your firm failed to initiate an investigation when the following maintenance reports were opened on the (b) (4) blister filling machine, during the blister pack filling process for (b) (4) gel caps and unbranded (b) (4) gel caps, following a jam in the machine which resulted in gel caps being sliced open at the punching station, spilling their contents onto the machine. This machine is also used to fill the PAI subject drug, (b) (4), ANDA (b) (4), into blister packs. The following Maintenance Reports document incidents of (b) (4) and/or (b) (4) gel caps being accidentally sliced open and spilling onto the machine, for which your firm failed to formally investigate:

A. Maintenance Report 13862, dated March 10, 2021, entitled, "Jam at Punch Station and Pill Bursts", for (b) (4) gel caps, Batch# (b) (4), March 19, 2021.

B. Maintenance Report 13999, dated September 7, 2021, entitled, "Jam at punch station causing burst capsules", for (b) (4) gel caps, Batch (b) (4), September 14, 2021

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Anastasia M Shields, Investigator Michele Gottshall, Investigator Brandy N Lepage, Investigator	<small>Anastasia M Shields Investigator Signed By: Anastasia M. Shields - Date Signed: 02-03-2022 18:03:57</small> X _____	DATE ISSUED 2/3/2022

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C. Maintenance Report 15340, dated January 21, 2022, entitled, "Product cut in Punch", for (b) (4) , Batch (b) (4) , January 24, 2022.

Additionally, section 12 of the (b) (4) and (b) (4) gel caps (b) (4) Instruction references an unvalidated equipment cleaning procedure for spills, leaks or burst capsules, (i.e. (b) (4) capsules (b) (4) Instruction", Document #WI/MPS3651/02.0).

OBSERVATION 2

Deviations from written production and process control procedures are not justified.

Specifically, the following change controls were opened by your firm after you experienced water leaking into production rooms through the ceiling, which were determined to be from leaks in the roof/duct work of the building:

- a. Change Request #180210 (10/3/2018)
- b. Change Request #180235 (10/29/2018)
- c. Change Request #190044 (2/14/2019)
- d. Change Request #190120 (5/13/2019)

Additionally, the following are examples of deviation investigations which you initiated to investigate roof leaking discrepancies in 2018: Deviation Report (DRF) #'s 18367, 18372, 18386, 18398, 18489 and 18503.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Anastasia M Shields, Investigator Michele Gottshall, Investigator Brandy N Lepage, Investigator	<small>Anastasia M Shields Investigator Signed By: Anastasia M. Shields - Date Signed: 02-03-2022 18:03:57</small> X _____	DATE ISSUED 2/3/2022

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On 1/19/2022, during a walk-thru of your facility, we observed employees conducting a clean-up of production room (b) (4), where (b) (4) drug products are filled into sachets. Your firm disclosed during the inspection that the employees were cleaning up after water leakage from the ceiling which came again from the leaking roof.

Room (b) (4) is used in the filling process of the PAI subject drugs, NDA# (b) (4) and NDA# (b) (4)

***DATES OF INSPECTION**

1/19/2022(Wed), 1/20/2022(Thu), 1/21/2022(Fri), 1/24/2022(Mon), 1/25/2022(Tue), 1/26/2022(Wed), 1/27/2022(Thu), 1/28/2022(Fri), 1/31/2022(Mon), 2/01/2022(Tue), 2/02/2022(Wed), 2/03/2022(Thu)

Michele Gottshall
Investigator
Signed By: Michele Gottshall -S2
Date Signed: 02-03-2022 18:04:24

Brandy N Lepage
Investigator
Signed By: Brandy N. Lepage -S
Date Signed: 02-03-2022 18:05:01

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Anastasia M Shields, Investigator Michele Gottshall, Investigator Brandy N Lepage, Investigator	<p align="right">Anastasia M Shields Investigator Signed By: Anastasia M. Shields - Date Signed: 02-03-2022 18:03:57</p> <input checked="" type="checkbox"/>	DATE ISSUED 2/3/2022

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."