DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse Rm900 2nd & Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875	8/29/2016-9/19/2016* FEI NUMBER 3009590582

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Robert M. Kelly , Director of Pharmacy

FIRM NAME	STREET ADDRESS
Central Admixture Pharmacy Services, Inc.	6580 Snowdrift Rd Ste 100
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Allentown, PA 18106-9331	Producer of 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

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

Specifically,

Your deviation investigation #37-160203-009 regarding microbial organisms isolated in your cleanroom environment between January 2016 and August 2016 is deficient in that:

A) The microbial contamination discovered as part of the environmental monitoring (EM) conducted on 01/18/16 on the (b) (4) (b) (4) for the micro-organism *Phoma Spp.*, was not addressed as part of the investigation.

On 01/18/16, (b) (4) was used in the production of (b) (4) units of Total Parenteral Nutrition (TPN) sterile IV products. The majority of these products are intended for use in neonatal intensive care unit (NICU) patients.

At the time of this event, your process for sterility testing of TPN products consisted of collecting (b) (4) samples of the components used in the production of TPN products. (b) (4) component samples are not representative of the sterility of finished TPN products.

There were two other instances of microbial contamination found in cleanroom ISO Class 5 areas during environmental monitoring samples collected on 04/20/16 ((b) (4) and 06/23/16

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	James M Mason, Investigator 9/19/2016 X James M Mason James M Mason Investigator Signed by: James M. Mason -S	9/19/2016

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse Rm900 2nd & Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875	8/29/2016-9/19/2016* FEI NUMBER 3009590582

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Robert M. Kelly , Director of Pharmacy	
FIRM NAME Central Admixture Pharmacy Services, Inc.	STREET ADDRESS 6580 Snowdrift Rd Ste 100
CITY, STATE, ZIP CODE, COUNTRY Allentown, PA 18106-9331	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drugs

(b) (4) , which both resulted in the destruction of the batches of product produced on those benches during those dates. However, in the case of the microbial contamination on 01/18/16, the TPN products made on (b) (4) were released and distributed for use.

B) The investigation states that positive environmental monitoring samples, collected from the (b) (4) were due to inadvertent touching of (b) (4) which are used to (b) (4)

The report concludes that these excursions have no impact on sterility or quality of finished sterile IV products. However, after having placed finished product on the (b) (4) , pharmacists working in the clean room perform different tasks which involve touching equipment and components used in ISO Class 5 environment.

Additionally, pharmacists may also touch surfaces (i.e. carts, telephones or other objects) in the cleanroom ISO Class 7 environment, after having potentially contaminated their gloves by touching the (b) (4) . Technicians working in the cleanroom would also be touching the same surfaces and then performing manipulations in the ISO Class 5 environment during the production of sterile IV products.

From 01/19/16 to 08/15/16, there have been 25 instances were micro-organisms were isolated from (b) (4) while working in the cleanroom environment.

C) The report concludes that since the implementation of the latest corrective actions on 08/05/16, which included (b) (4) and conducting a (b) (4) , there has been no count specifications exceeded. However, the report indicates that on 08/15/16 there were additional micro-organisms isolated in the (b) (4) which are still pending identification. Another sample collected on 08/01/16 is also still pending identification.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	James M Mason, Investigator 9/19/2016 X James M Mason James M Mason Investigator Signed by: James M. Mason -S	9/19/2016

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse Rm900 2nd & Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875	8/29/2016-9/19/2016* FEI NUMBER 3009590582

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Robert M. Kelly , Director of Pharmacy	
FIRM NAME	STREET ADDRESS
Central Admixture Pharmacy Services, Inc.	6580 Snowdrift Rd Ste 100
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Allentown, PA 18106-9331	Producer of Sterile Drugs

D) The (b) (4) were first identified as a potential root cause after the results of the environmental monitoring samples collected from (b) (4) between 02/08/16 and 03/02/16 were positive for micro-organisms. However, no additional environmental monitoring samples were collected from the (b) (4) in order to determine the effectiveness of your corrective actions.

OBSERVATION 2

Procedures describing the warehousing of drug products are not followed.

Specifically,

Your investigation for deviation #37-160203-009 indicates that as a result of the microbial contamination discovered during environmental monitoring conducted on 06/23/16 on (b) (4) , lot #37-204337 and 37-204363 of Oxytocin 30 units/500mL NS were destroyed.

A review of the batch records for these lots found that after being released for distribution on 06/29/16, the status of the lots was never changed to "rejected".

The rejection log section of the batch records indicates the batches were "expired" on 08/31/16.

The destruction log indicates that the batches were destroyed because they were "expired".

There is no record documenting that the batches were quarantined as a result of this investigation.

***DATES OF INSPECTION**

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	James M Mason, Investigator 9/19/2016 X James M Mason James M Mason Investigator Signed by: James M. Mason -S	9/19/2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse Rm900 2nd & Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875	8/29/2016-9/19/2016* FEI NUMBER 3009590582

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Robert M. Kelly , Director of Pharmacy

FIRM NAME	STREET ADDRESS
Central Admixture Pharmacy Services, Inc.	6580 Snowdrift Rd Ste 100
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Allentown, PA 18106-9331	Producer of Sterile Drugs

8/29/2016(Mon),8/30/2016(Tue),8/31/2016(Wed),9/01/2016(Thu),9/07/2016(Wed),9/13/2016(Tue),9/19/2016(Mon)

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

James M Mason, Investigator

9/19/2016

X James M Mason

James M Mason
Investigator
Signed by: James M. Mason -S

DATE ISSUED

9/19/2016