

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

DISTRICT ADDRESS AND PHONE NUMBER 6751 Steger Drive Cincinnati, OH 45237-3097 (513) 679-2700 Fax: (513) 679-2772	DATE(S) OF INSPECTION 10/26/2015-1/21/2016* FBI NUMBER 3003693389
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
Thomas W. Kelsey , Regional Director, Pharmacy Operations

FIRM NAME Central Admixture Pharmacy Services Inc	STREET ADDRESS 8300 Sweet Valley Dr
CITY, STATE, ZIP CODE, COUNTRY Valley View, OH 44125-4263	TYPE ESTABLISHMENT INSPECTED Producer of 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**

Equipment and utensils are not maintained at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically, failure to assure that the (b) (4) (b) (4) used by your firm for producing sterile drugs, removes residuals of ingredients used in sterile drug production from previous bags of sterile drugs produced that day. The (b) (4) has (b) (4)

After each individual ingredient is added to the (b) (4) Each sterile drug produced by your firm does not use all (b) (4) ingredients. Your firm produces approximately (b) (4) of sterile drug product per day on the (b) (4). Your firm uses (b) (4). There is no assurance that residues from ingredients used during previous sterile drug production from that day are not transferred to the next sterile drugs being produced on the (b) (4) (b) (4). Furthermore, your firm has not performed any validation studies to assure that residuals are not remaining in the (b) (4) prior to filling the next bags throughout the day.

**OBSERVATION 2**

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.

Specifically, during media fills, failure to assure that all individuals involved in producing bags of sterile drug product on the (b) (4) perform all interventions that are identified to occur during routine

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Nicholas L Paulin, Investigator Michael P Sheehan, Investigator	<input checked="" type="checkbox"/> Nicholas L Paulin <small>(b)(4) Health Investigator Signed by: Nicholas L Paulin-1</small>	DATE ISSUED 1/21/2016

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sterile drug production. Your records indicate that interventions are the (b) (4) [redacted] For example:

- A media fill was performed by employees (b) (6) and (b) (6) on (b) (4) on (b) (4) [redacted], bench 1. The only intervention performed by (b) (6) was the (b) (4) [redacted]. Employee (b) (6) did not perform any interventions for (b) (4) (b) (4) but performed interventions of the (b) (4) [redacted].
- A media fill was performed by employees (b) (6), and (b) (6) on (b) (4) on (b) (4) [redacted], bench 2. The only intervention performed by (b) (6) was the (b) (4) [redacted]. Employee (b) (6) performed only (b) (4) [redacted]. Employee (b) (6) performed interventions of (b) (4) [redacted].

**OBSERVATION 3**

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

Specifically, your firm produced and distributed a sterile drug product for Cardioplegia. Your firm ceased production of this product in September 2015 from this facility. Per your Regional Director of Pharmacy Operations, your firm routinely delivered the filled bags to customers for use prior to obtaining sterility results of the finished product.

For example, on 09/10/15, your firm produced (b) (6) Cardioplegia bags (b) (4) [redacted] on the (b) (4) [redacted] (b) (4) #1. On 9/13/15, your firm delivered (b) (4) of the Cardioplegia bags (Rx (b) (4), (b) (6) (b) (4) bag; Rx (b) (4), (b) (6) and Rx (b) (4), (b) (6); (b) (4) bags) that were produced on pump #1 on 09/10/15 to a customer located in Cleveland, OH via a (b) (4) [redacted] under packing list (b) (4) [redacted]. Your firm did not complete sterility testing until 9/20/15 and approved the sterility testing results of the finished

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EMPLOYEE(S) SIGNATURE  
Nicholas L Paulin, Investigator  
Michael P Sheehan, Investigator

Nicholas L Paulin  
Investigator  
Employee Number: [redacted]

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product on 9/21/15, eight days after you distributed the product. Your firm has no limitation on when the Cardioplegia product is to be administered.

**OBSERVATION 4**  
Clothing of personnel engaged in the processing of drug products is not appropriate for the duties they perform.

Specifically,

(a.) Your firm's employees do not wear eye protection during production activities in your ISO 7 clean room and ISO 5 hoods. During the inspection, we observed employees wearing a sterile hood which covers their entire head with the exception of an opening which leaves their eyes, eyelashes and eyebrows exposed and uncovered to the environment. These employees do not wear any goggles or a face shield. These employees were observed producing sterile products underneath the ISO 5 hoods.

(b.) Firm personnel (b) (4) in the sterile compounding ISO 7 clean room and for processing of sterile drug products in the ISO 5 hoods. Your management identified that the (b) (4).

**OBSERVATION 5**  
Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room to produce aseptic conditions.

Specifically, (b) (4) a non-sterile detergent, used for cleaning floors in the classified areas of your facility is not sterilized prior to use.

**\*DATES OF INSPECTION**  
10/26/2015(Mon),10/27/2015(Tue),10/28/2015(Wed),10/29/2015(Thu),10/30/2015(Fri),11/05/2015(Thu),1/20/2016(Wed),1/21/2016(Thu)

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	<input checked="" type="checkbox"/> Nicholas L Paulin Investigator Signed by: Nicholas L. Paulin, Investigator	

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1/21/2016

Michael P Sheehan

Michael P Sheehan  
Investigator  
Signed by: Michael P. Sheehan -S

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