DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313)393-8139	11/16/2015-12/4/2015* FEI NUMBER 1000306306

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Glenn J. Pangrazzi , Director of Pharmacy

FIRM NAME	STREET ADDRESS
Central Admixture Pharmacy Services, Inc.	37497 Schoolcraft Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Livonia, MI 48150-1007	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

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and followed .

Specifically,

The aseptic practices and techniques observed at your facility are inadequate in that:

i. Several instances were observed where non-sterile items were not fully decontaminated when moved from the (b) (4) . For example, on 11/17/15, an operator working in ISO 5 workstation (b) (4) was observed to spray a large glass drug component bottle on the top and one side with sterile (b) (4) as it was placed into the ISO 5 work area during aseptic processing of a TPN product. The back and underside of the bottle were not sanitized or decontaminated in any way.

ii. Operators working in the ISO 5 areas on 11/17/15 were observed to exhibit quick, rather than slow and deliberate, movements when performing critical operations such as aseptic connections of raw materials to the (b) (4) during aseptic filling of TPN products in ISO 5 workstations (b) (4) and (b) (4)

iii. Exposure to first air from the HEPA filters in the ISO 5 workstations is not always maintained for critical surfaces. For example, on 11/17/15 an operator's gloved hands were directly above the sanitized septum of a raw material bottle immediately prior to (b) (4) during filling of a TPN bag in ISO 5 workstation (b) (4). Additionally on this same day in ISO 5 workstation (b) (4), an operator was observed to place raw material bottles underneath equipment located in the ISO 5 area after the septum had been sprayed with sterile (b) (4) and just prior to (b) (4) (b) (4) during filling of a TPN bag.

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iv. On 11/17/15 an operator was observed to spray the septum of a raw material bottle with sterile (b) (4) (b) (4) and within five seconds (b) (4) during filling of a TPN bag on workstation (b) (4). SOP 4000175, *Aseptic Technique*, requires that (b) (4) for (b) (4)

OBSERVATION 2

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

Specifically,

Gowning of operators performing aseptic operations in the ISO 5 areas is inadequate in that the current method of gowning leaves facial skin exposed around the eyes and forehead. Additionally, gowns that are initially sterile are hung in the ISO 8 gowning room after use and (b) (4)

This observation applies to all injectable drug products made at this facility, for example, TPN bag (CAPS Rx number (b) (4), (b) (6)) processed in ISO 5 workstation (b) (4) on 11/11/2015.

OBSERVATION 3

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

Specifically,

i. Data was not provided to support that the disinfectant efficacy studies performed are equivalent to current cleaning practices. (b) (4) states to (b) (4) (b) (4) However, SOP 4000183, *Cleaning Procedure*, describes cleaning of most surfaces within the ISO 5 areas by (b) (4)

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ii. The ISO 5 area contains threaded bolts and hinges that do not appear to be easily cleanable and may harbor contamination. Currently, the walls and ceiling of the ISO 5 areas are cleaned with (b) (4) (b) (4) , and data was not provided to assure this method of cleaning is adequate for these hard to clean surfaces.

This observation applies to all injectable drug products made at this facility, for example, TPN bag (CAPS Rx number (b) (4), (b) (6) processed in ISO 5 workstation (b) (4) on 11/11/2015.

OBSERVATION 4

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

i. Environmental monitoring (EM) performed at your facility is inadequate in that such is not performed during every drug processing shift in the critical areas. Currently, sterile drug processing occurs (b) (4) (b) (4) However, active viable, non-viable particulate, and surface (b) (4) EM is collected (b) (4) Personnel monitoring (b) (4) is performed (b) (4)

ii. The monitoring frequency of pressure differentials between the aseptic processing room (ISO 7) and surrounding areas of lower air quality (ISO 8 and unclassified) is not justified. Currently, pressure differentials are checked and documented (b) (4) . Assurance was not provided to support that a temporary loss in differential pressure during filling operations would be detected and appropriately handled.

This observation applies to all injectable drug products made at this facility, for example, TPN bag (CAPS Rx numbe (b) (4), (b) (6)) processed in ISO 5 workstation (b) (4) on 11/11/2015.

OBSERVATION 5

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The operations relating to the processing of penicillin are not performed in facilities separate from those used for other drug products for human use.

Specifically,

Adequate segregation of personnel and materials relating to beta-lactam drug products from other human injectable drug products is not performed. Processing of beta-lactam drug products occurs in the (b) (4) SOP 4000196 requires (b) (4) (b) (4) however, no documentation of decontamination and/or cleaning was provided for examples reviewed including:

piperacillin/tazobactam 4.5g/100ml (CAPS Rx(b) (4), (b) (6)), made on 9/18/15
ampicillin 2gm/100ml NS (MB) (CAPS Rx(b) (4), (b) (6)), made on 9/19/15

THIS IS A REPEAT OBSERVATION

***DATES OF INSPECTION**
11/16/2015(Mon),11/17/2015(Tue),11/18/2015(Wed),11/19/2015(Thu),12/04/2015(Fri)

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