DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	9/16/2021-9/28/2021* FEI NUMBER 1972829

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Melissa R. Mays, Director of Pharmacy

FIRM NAME	STREET ADDRESS
SSM Health Care St. Louis DBA SSM St. Clare Health Center	1015 Bowles Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fenton, MO 63026-2394	Outsourcing Facility

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

Written records of investigations into the failure of a batch or any of its components to meet specifications do not always include the conclusions and follow-up.

Specifically,

A. On 09/17/2021, I observed visibly wet, apparently leaking, IV bags containing Potassium Chloride 40 mEq in 270 mL 0.9% Sodium Chloride for injection, lot (b) (4). The IV bags were in a (b) (4)-unit case, which had already passed 100% visual inspection. The 0.9% sodium chloride IV bags used to compound Potassium Chloride 40 mEq in 270 mL 0.9% Sodium Chloride for injection, lot (b) (4), were from bag manufacturer lot (b) (4) I then observed two wet puddles on the prep cart used to stage IV bags for the next batch of product, which had passed initial inspection when removing the outer bag from the IV bags. The 0.9% sodium chloride IV bags on the cart were also from bag manufacturer lot (b) (4) Your Operations Pharmacist showed me a tray of approximately (b) (4) leaking bags of 0.9% sodium chloride, which he discovered and quarantined when staging the prep cart.

You stated you have found approximately (b) (4) leaking bags from 0.9% sodium chloride IV bags, lot (b) (4), when compounding previous lots going back to 08/06/2021. You distributed (b) (4) units from lot (b) (4) of Potassium Chloride 40 mEq in 270 mL 0.9% Sodium Chloride for injection to (b) (4) hospitals after already identifying leaking bags from the bag manufacturer lot (b) (4). In addition, you had (b) (4) other lots of Potassium Chloride 40 mEq in 270 mL 0.9% Sodium Chloride for injection compounded

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from the same IV bag lot on hand in quarantine status, which were awaiting sterility test results in order to be released.

B. Your corrective and preventive actions (CAPA) taken in response to the environmental monitoring (EM) and personnel monitoring (PM) failing results from your sterile compounding technician, (b) (6) are ineffective as evident by repeated occurrences of the same issue. This employee's EM and PM results have been repeatedly above the alert and action limits since February 2020, as seen in the following table:

Date Compounded	Product	Lot	Site	Site	CFU Count	Batch Disposition
2/19/2020	Oxytocin	(b) (4)	Personnel, Surface	(b) (4)	8	Destroyed
5/19/2020	Fentanyl Vials		Personnel, Surface		3	Destroyed
	Fentanyl Vials		Personnel, Surface		3	
7/22/2020	Neostigmine		Personnel, Surface		2	Released
9/16/2020	Norepinephrine		Personnel, Surface		1	Destroyed
9/23/2020	Neostigmine		(b) (4)		1	Destroyed
	Neostigmine		(b) (4), Surface		1	
10/20/2020	Fent/Ropi		(b) (4),		1	Destroyed

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	Epidurals	(b) (4)	(b) (4)	(b) (4)	
	Fent/Ropi Epidurals			1	
11/30/2020	Potassium		Personnel, Surface	3	Released
2/10/2021	Potassium		Personnel, (b) (4)	1	Destroyed
	Potassium		Personnel, (b) (4)	2	
2/12/2021	Potassium		(b) (4)	1	Destroyed
2/19/2021	Oxytocin		Personnel, Surface	7	Destroyed
3/19/2021	Oxytocin		Personnel, (b) (4)	2	Destroyed
	Oxytocin		Personnel, (b) (4)	1	
4/9/2021	Fentanyl Vials		Personnel, Surface	5	Released
	Fentanyl Vials		Personnel, Surface	1	
4/13/2021	Diltiazem		Personnel, Surface	1	Released
4/30/2021	Potassium		Personnel, (b) (4)	4	Destroyed
5/7/2021	Oxytocin		Personnel, Surface	1	Released
8/27/2021	Potassium		(b) (4) Surface	11	Destroyed

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	Potassium	(b) (4)	Personnel, Surface	(b) (4) 7	
9/14/2021	Succinylcholine		(b) (4) Surface	5	Destroyed
	Succinylcholine		Personnel, (b) (4)	2	
9/16/2021	Norepinephrine		(b) (4)	12	Destroyed

Out of (b) (4) batches compounded by employee (b) (6) from February 2020 to September 2021, you rejected 13 of them, or (b) (4)%, due to environmental monitoring and personnel monitoring failures. You investigated these deviations and wrote CAPAs for them, but the CAPAs were ineffective based on repeat occurrences of the same type of problem. For example, CAPA QAL-20-015, issued on 12/22/2020, states employee (b) (6) shall be routinely observed to ensure proper aseptic technique is used. However, on 04/05/2021, for the CAPA effectiveness follow up for CAPA QAL-20-015 concludes "However, EM growth still routinely seen." There were no additional CAPAs put in place or comments due to the environmental monitoring (EM) growth being found.

OBSERVATION 2

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

Specifically,

Your visual inspection program is inadequate as evidenced by the following:

A. It lacks defined defect categories, such as critical, major, and minor. Your SOP OPS.007, Visual Product Check, effective 08/09/2021, mentions checking for critical, major, and minor defects during visual inspection qualification, but it does not define what types of defects fall under each category. In

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addition, your firm compounds sterile drugs in IV bags, syringes, and vials. You have no defined defect types specifically for IV bags, syringes, and vials.

B. You have no established threshold for defects found during visual inspection as it relates to the disposition of the batch.

C. Your visual inspection qualification kit is comprised of bags, vials, and syringes taken from production. The defects in the kit are coring particles in an IV bag. The visual inspection qualification kit does not contain defects in a syringe or a vial. There is no documentation identifying the defect category core particles are classified as, based on a scientifically established risk assessment. There are no defects in vials or syringes for the visual inspection qualification kit.

D. Based on your visual inspection qualification records, employees inspect (b) (4) units from the visual inspection kit for their qualification. Their answers are not scored. Some employees are given (b) (4) "passing" units with no defects. You have (b) (6) employees who are "qualified" for visual inspection even though they have not identified a defect in a controlled setting during qualification.

E. You do not require employees engaged in visual inspection operations to undergo an eye exam.

OBSERVATION 3

Written procedures are lacking which describe in sufficient detail the receipt, identification, testing, approval and rejection of components, drug product containers and closures.

Specifically,

A. You stated you do not inspect critical components upon receipt, including, but not limited to, sterile 0.9% sodium chloride IV bags and sterile vials of bulk drug substances. You stated critical components are looked at while preparing for compounding operations, but there is no officially documented inspection step. In addition, you have not established any thresholds for rejecting a batch of critical components based on the number of defects found during routine inspections or downstream visual inspection operations.

B. You stated you do not perform identity testing on received sterile vials of drug products used in the

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compounding of sterile drug products. The received sterile drug products include, but are not limited to, (b) (4) and (b) (4) (b) (4)

OBSERVATION 4

The labels of your outsourcing facility's drug products are deficient.

Specifically,

A. The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A). Specifically, the following information is not found on your drug product labels:

i. The dosage form and strength;

Examples of your product labels that do not contain this information:

- Fentanyl citrate 2 mcg/mL and ropivacaine HCl 0.2% in 0.9% Sodium Chloride 150mL
- Norepinephrine bitartrate 8 mg in dextrose 5% 250mL (0.032mg/mL)
- Diltiazem HCl 125 mg in 0.9% Sodium Chloride 125 mL (1mg/mL)
- Potassium Chloride 40 mEq in 0.9% Sodium Chloride 270mL
- Oxytocin 30 units in 0.9% Sodium Chloride 500 mL (0.06 units/mL)
- Fentanyl citrate 10 mcg in 0.9% Sodium Chloride (10 mcg/mL) (1ml vial)
- Neostigmine methylsulfate 5 mg in 5 mL (1 mg/mL) (5 mLs in 10mL syringe)
- Succinylcholine Chloride 100 mg in 5 mL (20 mg/mL)

B. The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(B). Specifically, the following information is not found on your drug product container labels:

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i. A list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient.

Examples of your product container labels that do not contain this information:

- Morphine sulfate 50 mg in 0.9% Sodium Chloride 50 mL syringe (1 mg/mL)
- Norepinephrine bitartrate 8 mg in dextrose 5% 250mL (0.032mg/mL)

***DATES OF INSPECTION**

9/16/2021(Thu), 9/17/2021(Fri), 9/20/2021(Mon), 9/21/2021(Tue), 9/22/2021(Wed), 9/23/2021(Thu), 9/24/2021(Fri), 9/27/2021(Mon), 9/28/2021(Tue)

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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."