DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Dr., Suite 205 Lenexa, KS 66214 (913) 495-5100	01/29/2024 – 02/08/2024
	FEI NUMBER 1972829
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Kristina N. Bryowsky, Pharm D, Regional Vice President	
FIRM NAME SSM Health Care St. Louis DBA SSM St. Clare Health Center	STREET ADDRESS 1015 Bowles Ave
CITY, STATE, ZIP CODE, COUNTRY Fenton, MO 63026-2394	TYPE ESTABLISHMENT INSPECTED 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 WE OBSERVED:

OBSERVATION 1

Your firm failed to establish written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically,

A. You observed two potency failures for Morphine Sulfate 50 mg in 50 mL of NS (1 mg/mL). OOS QAL-22-016, batch (b) (4) occurred on approximately 2/2/2022 with a result of 206.5% (2.1 mg/mL) and OOS QAL-22-059, batch (b) (4) occurred on approximately 11/10/2022 with a result of 76.0% (0.8 mg/mL). Your specification is (b) (4) Each of these failures were considered confirmed product failures. While you implemented interim CAPA-22-003 (b) (4) (b) (4)(b) (4), it was not effective until approximately 5/16/2022. During this period (02/2022 – 5/2022) you made (b) (4) more batches of Morphine Sulfate 50 mg in 50 mL of NS (1 mg/mL). This new batch (b) (4) step was not documented during the manufacturing of these batches of Morphine Sulfate. Furthermore, OOS QAL-22-059, batch (b) (4) occurred on approximately 11/10/2022, after the firm implemented Change Control CC-22-003, performed in response to the initial Morphine Sulfate failure on approximately 2/2/2022. Process validation has not been performed specifically regarding the (b) (4) of Morphine Sulfate.

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	Robert J. Ham, Investigator	Robert J. Ham -S Digitally signed by Robert J. Ham -S Date: 2024.02.08 14:07:38 -06'00'	02/08/2024

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B. You have not performed process validation regarding Morphine Sulfate 50 mg in 50 mL of NS (1 mg/mL). In addition, you have not performed process validation regarding Phenylephrine HCl 1000 mcg in 10 mL of NS (100 mcg/mL) in 10 mL, Fentanyl Citrate 10 mcg in 1 mL of NS (10 mcg/mL) or Hydromorphone HCl 10 mg in 50 mL of NS (0.2 mg/mL) drug products. Additionally, (b) (4) tested from each production batch and Phenylephrine batches approximate (b) (4) units. Each of these drug products are mixed with a (b) (4) such as (b) (4) in concentrations ranging from ((b) (4)). You have made the following batches since approximately 2022:
- Morphine Sulfate 50 mg in 50 mL of NS (1 mg/mL): (b) (4)
- Hydromorphone HCl 10 mg in 50 mL of NS (0.2 mg/mL): (b) (4)
- Phenylephrine HCl 1000 mcg in 10 mL of NS (100 mcg/mL) in 10 mL: (b) (4)
- Fentanyl Citrate 10 mcg in 1 mL of NS (10 mcg/mL): (b) (4)

OBSERVATION 2
Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

A. The aseptic processing area is not adequately monitored during production. In addition, there is a lack of scientific rationale behind the selection process for the monitoring locations, and there is insufficient data to ascertain whether these chosen sites produce significant or meaningful results.
   1. The active viable monitoring is only performed after production activities have ceased. In addition, the active viable air monitoring device is placed against the back wall of the right ISO 5 Laminar Flow Hood. This placement could bias the readings towards the conditions directly adjacent to the filter, providing an inaccurate representation of the overall air quality within the hood.

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2. Non-Viable Particle (NVP) monitoring is conducted in the ISO 5 Laminar Flow Hood prior to and after the conclusion of production activities. The location of the monitor is facing the (b) (4) of the ISO 5 Laminar Flow Hood. For the remainder of the production activities, the NVP monitor is located (b) (4) of the ISO 5 Laminar Flow Hood and (b) (4) the production activities.
3. During production of lot 20240130-10515F on January 30, 2024, I observed the settle plate placed in the (b) (4) of the ISO 5 Laminar flow hood. It was located directly behind a spray bottle of (b) (4) used to spray surface area and production technician (b) (6), (b) (7) hands, forearms and chest throughout the compounding process. It is unclear if droplets of (b) (4) come into contact with the settle plate and potentially inhibit microbial growth. In addition, most of the compounding activities take place in the (b) (4) of the ISO 5 Laminar Flow Hood.
4. (b) (4) surface samples are collected at the conclusion of compounding activities. (b) (4) samples are taken on the (b) (4) work surface of the ISO 5 Laminar flow hood. Sterile compounding environments typically consist of multiple work surfaces, equipment, and areas that could harbor contaminants. Sampling only one surface may not capture variations in cleanliness across different areas.

B. Production Technician Monitoring – Production Technician Monitoring lacks scientific justification for its frequency and acceptance limits. Monitoring is limited to (b) (4) for each batch. While technicians in the ISO 5 laminar flow hood are (b) (4) sampled on the (b) (4) these sample locations are held to ISO 7 standards, not ISO 5. During production of lot 20240130-10515F on January 30, 2024, Investigator Ham and I observed production technician (b) (6), (b) placing additional body parts, like the head, chest, and forearms, into the ISO 5 area. Gowning pieces that are in close proximity to the product can be a source of contamination.

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OBSERVATION 3

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,

According to a trending report dated 1/1/2022-1/2/2023, 503A penicillin and beta lactam products were consistently compounded inside the 503B hood (b) (4) during 2022 and for (b) (4) of 2023. During this timeframe, over (b) (4) instances of 503A compounding beta lactam product including but not limited to ampicillin and penicillin in the same hood 503B compounding production activities are performed in were documented. Examples include but are not limited to:

4/4/2023	PENICILLIN G POTASSIUM UP TO 3 MU IN 50 ML (b) (4)
4/4/2023	PENICILLIN G POTASSIUM UP TO 3 MU IN 50 ML (b) (4)
7/22/2023	AMPICILLIN-SULBACTAM 1.5 G IN 50 ML (b) (4)
7/22/2023	AMPICILLIN-SULBACTAM 1.5 G IN 50 ML (b) (4)
7/24/2023	MEROPENEM 1000 MG IN 50 ML (b) (4)
7/24/2023	MEROPENEM 1000 MG IN 50 ML (b) (4)
7/24/2023	CEFAZOLIN 1G POCKET FLUSH (b) (4)
7/24/2023	ERTAPENEM 1000 MG IN 50 ML (b) (4) (USING (b) (4) VIAL) (b) (4)

OBSERVATION 4

An adequate number of batches of each drug product are not tested to determine an appropriate expiration date.

Specifically,

You discontinued your stability program in 2022 per your site leadership personnel. You have continued to produce various drug products to include but not limited to approximately (b) (4) lots of

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Phenylephrine HCl 1000 mcg in 10 mL of NS (100 mcg/mL) in 10 mL in lot sizes approximating (b) (4) units.

OBSERVATION 5

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

Specifically,

A. On January 30, 2024, I observed a stain on the HEPA filter located in the ISO 5 Laminar Flow Hood used during the compounding of lot (b) Fentanyl 2mcg/mL and Ropivacaine 0.2% in 0.9% sodium chloride 150mL. Total units compounded were (b) (5), (b) /150mL bags.
B. While conducting cleaning procedures prior to the beginning of compounding on Tuesday January 30, 2024, it was observed that the production technician cleaned the computer tablet, the mount securing the tablet to the exterior of the right ISO 5 Laminar Flow Hood, and the wires situated outside the ISO 5 laminar flow hood. Subsequently, the same wipe was employed to clean the Repeater pump located inside the ISO 5 laminar flow hood.

OBSERVATION 6

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

Specifically,

The following observations were noted while observing the aseptic compounding of (b) (4) /150mL units of lot (b) (4) Fentanyl 2mcg/mL and Ropivacaine 0.2% in 0.9% sodium chloride 150mL:

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A. Production technician gowning coming into direct contact with the top of exposed septa of fentanyl vials.
B. Blocking first air while removing the cap which exposes the septum of the fentanyl vial as well as when removing the cap covering the injection port of the finished product IV bags.
C. (b) (4) the outer packaging of components instead of (b) (4) the packaging open while inside the ISO 5 Laminar flow hood.

OBSERVATION 7

Employees engaged in the manufacture and processing of a drug product lack the training required to perform their assigned functions.

Specifically,

A. The AQL visual inspection lacks scientific justification for acceptable limits on critical, major, and minor defect levels. Furthermore, there is an absence of established in-process limits for critical and major defects during the visual inspection process.
B. Your visual inspection qualification (b) (4) and the master defect log are not access controlled. You allow visual inspectors who perform AQL inspections access to your qualification (b) (4) without restriction. These (b) (4) are used to initially qualify and (b) (4) requalify all visual inspectors. In addition, all units in the certification (b) (4) are numbered. Unlimited access to a single visual inspection (b) (4) with numbered units raises concerns about the potential for operators to memorize the (b) (4), which could compromise the accuracy of the visual inspection process.
C. You are not documenting the duration of operator qualification on inspection (b) (4) Furthermore, Visual Inspection operators are not required to wear the same type of visual corrective aids used during qualification when performing routine production visual inspections. These practices could increase the potential for inconsistent performance.

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D. There is no requirement to conduct a 360-degree visual inspection of each unit. While watching the 100% visual inspection of (b) (4) Fentanyl drips 50mcg/ml in 50mg bag on February 2, 2024, the visual inspector held the bag in front of the (b) (4), (b) (4) the bag then repeated the same process in front of the (b) (4) without looking at both the front and back of the bag in front of (b) (4).

E. The qualification and requalification grading processes lack a breakdown of critical, major, and minor defects that were missed, and there is an absence of recorded information regarding acceptable units rejected.

OBSERVATION 8

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. You failed to initiate investigations regarding inadequate cleaning in the ISO 5 laminar flow hood. On January 30, 2024, an area of apparent rust was observed in the ISO 5 laminar flow hood. Your QA manager stated this was actually oxidized (b) (6), (b) (7)(C) residue. When asked how she knew this, she reported we have seen it before. As of February 7, 2024, there is no record of an investigation initiated for this quality event.

B. There is no record of an investigation or a planned deviation when new equipment must be temporarily introduced into the ISO 5/7 area. For example, when compounding batch (b) (4) (b) (4) Phenylephrine HCl 1000 mcg in 10 mL of NS in 10 mL (b) (4) Syringe, a note stating: "There were issues with the normal cleanroom tablet connecting to the WiFi during the batch. The backup tablet was cleaned and used during part of the batch by the operator.". This planned deviation was not documented. In addition, a possible root cause for deviation QAL-232-040 initiated on 9/19/2023 was listed as: "The backup tablet typically is held in the Outsourcing area.

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(b) (4) website was not allowing camera use and then the tablet froze and wouldn't function at all. The backup tablet was cleaned and put through the (b) (4) but was not connected to the arm as we do not have 2 cases and switching the cases consumes a lot of time and requires IT involvement. The possible root cause at this time is the use of (b) (4) and (b) (4) (b) (4) .

C. No investigation was initiated for growth promotion failure of (b) (4) media lot# (b) (4). In addition, (b) (4) media lot# (b) (4) was also recorded as having no CFUs for growth promotion on 4/19/2023. When brought to the attention of the Production Technician on 1/30/2024, he changed the CFU result to "TNTC" and dated the correction "1/30/2024". When asked how he knew the (b) (4) media from April grew TNTC colonies, he explained all the plates have been TNTC for a long time. No investigation was initiated at the time of the original result of no growth.

D. From March 29, 2023, through September 19, 2023, four environmental monitoring investigations were initiated due to the same Production Technician's recurrent failures. No root causes were identified and CAPA's implemented as a result of and these investigations were not effective. During this time frame Production Technician (b) (6), (b) (compounded (b) (4) batches, two of which were rejected.

REPEAT OBSERVATION (2020)

OBSERVATION 9

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

1. Specifically, the following information is not found on your labels:
   a) The statement "This is a compounded drug";
   b) The name, address, and phone number of the outsourcing facility;

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c) The lot or batch number;
d) Date that the drug was compounded;
e) The storage and handling instructions;
f) The statement "Not for resale"
g) Subject to paragraph (B)(i), a list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient
h) The following information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088

Examples of your labels that do not contain all or some of the required information specified above:

- Order # (b) (6), (b) (7)(C), (b) (4) ertapenem (b) (4) 1,000mg in 0.9% NaCl IV 50mL IVPB
- Order# (b) (6), (b) (7)(C), (b) (4) ampicillin-sulbactam (b) (4) 1.5g in 0.9% NaCl IV 50mL IVPB
- Order # (b) (6), (b) (7)(C), (b) (4) for Sodium Bicarbonate 8.4% 150mEq in dextrose 5% infusion (fluid)
- Order (b) (6), (b) (7)(C), (b) (4) for Chlorpromazine (b) (4)) 25mg in 0.9% NACl IV 50mL infusion
- Order # (b) (6), (b) (7)(C), (b) (4) for (b) (4) (b) (4) infusion
- Order # (b) (6), (b) (7)(C), (b) (4) Lidocaine (b) (4) 1% 30mL, Epinephrine 1mg/1mL , sodium bicarbonate 8.4% 12.5mEq, tranexamic acid (b) (4) 1,000mg in 0.9% NaCl IV infiltration
- Fentanyl citrate 2500mcg/50mL IV

OBSERVATION 10

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Your outsourcing facility did not submit a report to FDA identifying all of the drugs compounded during the previous six-month period. Examples of drug products that were compounded and not identified on your report dated December 2023, include, but are not limited to.:

- Order #(b) (4), (b) (6), (b) (7)(C) for Sodium Bicarbonate 8.4% 150mEq in dextrose 5% infusion (fluid)
- Order #(b) (4), (b) (6), (b) (7)(C) for Chlorpromazine (b) (4) 25mg in 0.9% NACl IV 50mL infusion
- Order #(b) (4), (b) (6), (b) (7)(C) for(b) (4) (b) (4) infusion
- Order #(b) (4), (b) (6), (b) (7)(C) Lidocaine (b) (4) 1% 30mL, Epinephrine 1mg/1mL , sodium bicarbonate 8.4% 12.5mEq, tranexamic acid(b) (4)) 1,000mg in 0.9% NaCl IV infiltration

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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."