DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Kansas City District Office 8050 Marshall Drive, Suite 205 Lenexa, KS 66214 913-495-5100 Fax: 913-495-5115 Industry Information: www.fda.gov/oc/industry	8/4-7&14/2014
	FEI NUMBER 1972829

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Kristina N. Bryowsky, PharmD, BCPS, Director Pharmacy

FIRM NAME	STREET ADDRESS
SSM Health Care St. Louis DBA SSM St. Clare Health Center	1015 Bowles Avenue
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Fenton, MO 63026	Compounding 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) (WE) OBSERVED:

Observations below relate to the following compounded products by your hospital: Amiodarone 900mg in D5W 500mL, Nicardipine 25mg in 0.9% Sodium Chloride 250mL, Oxytocin 30 units in 0.9% Sodium Chloride 500mL and Norepinephrine 8mg in D5W 250mL.

1. Clothing of personnel engaged in compounding drug activities is not appropriate for the duties they perform. Specifically,

a. All gowning components worn in the ISO 7 Clean Room for aseptic operations in the ISO 5, IV Hood are not labeled as sterile. Bouffant cap, shoe covers, surgical mask and gown are not labeled as sterile. Only gloves used are labeled as sterile. All these gowning supplies are single use and stored open on shelves in the ante room (ISO 7 per last HEPA re-certification). In addition, the Pharmacy Policy, Subheading Hand Hygiene and Garbing Procedure do not allow jewelry in the clean room. On 8/5/2014, personnel were observed with a necklace and on 8/6/2014 observed with rings.

b. On 8/5 and 6/2014 personnel were observed with exposed skin around the neck and face performing aseptic operations. Goggles are not required per Pharmacy Policy. Personnel wear hair cover and surgical mask.

2. Procedures designed to prevent microbiological contamination of compounded drug products purporting to be sterile are not followed. Specifically,

a. On 8/6/2014, operator was observed to drop the tubing with a needle, allowing the needle to touch the counter top, then continued with the compounding process. This occurred during the compounding of Lot Number 140806-1185 Oxytocin 30 units in 500 mL bags.

b. On 8/6/2014, operator was observed to drop an IV bag of Sodium Chloride 0.9% IV Solution when removing it from the cart to place it in the IV Hood. The IV bag is used in Lot Number 140806-1185 Oxytocin 30 units in 500 mL bags, on the floor in the Clean Room. The operator pick up the bag, sprayed it with (b) (4) rub the bag with gloved hands, and place it at the end of the row for compounding. The operator then sanitized his hands. The operators sanitized the end of the port prior to compounding with (b) (4) The

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	Shirley J Berryman	Shirley J. Berryman, Investigator	8/14/2014

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firm did not assess the impact of these occurrences on sterility assurance.

3. You have failed to conduct Environmental Monitoring in your ISO 5, IV rooms (where drug products are compounded). Specifically, you have not conducted daily air, surface and personnel monitoring when compounding sterile products listed above from April 14, 2014 – August 6, 2014 (Days compounding – (b) (4) (b) (4) . You have only conducted (b) (4) swab sample in the hood. In addition, you do not have a procedure for environmental monitoring of your ISO 5 area and personnel monitoring covering compounding operations.

4. You failed to have a smoke study procedure used to evaluate your ISO 5 IV hood under dynamic conditions and you have not conducted a smoke study since the IV Hood was installed in 2009.

5. Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the equipment to produce aseptic conditions where compounding activities occur. Specifically,

a. No sterile sporicidal disinfectant is used on the surfaces in the ISO 5 IV Hood. Only (b) (4) and (b) (4) (b) (4) are used.

b. Non-sterile non-shedding wipes are used for cleaning in the ISO 5 IV Hood .

c. On 8/5/2014 white cushion tape had shifted during the cleaning process and was observed hanging down a couple inches in the IV hood.

6. The 100% visual check is not conducted with a contrasting background but held up to the light or held near the back where the HEPA filter in the ISO 5 IV Hood is located for the darker background (observed on 8/6/2014). The second check by the Pharmacist was observed on 8/5/2014 in the Ante Room with only the light background.

7. All batch product records from April 14 – August 6, 2014 are inadequate for the compounded products listed above. The batch product record is not a reproduction of the master record; it does not document each significant step, inspection of packaging and labeling, actual and theoretical yield, and identification of persons performing significant steps. The single page is generated from (b) (4) software with headings for Compounding and Repackaging Drug Production, Ingredients, Recipe, and Pharmacist Signature. A copy of the label is attached and a hand written note with the amount of bag(s) sent for testing.

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8. Sterile containers/product contact surfaces such as but not limited to: transfer tubing, 3000mL IV Bags (used in the compounding process) are accepted without testing for sterility and endotoxin levels or reviewing/examining the manufacturer's certificate of analysis.

9. The responsibilities and procedures are not in writing and fully followed. Specifically, there are no procedures on site for the following areas regarding your compounded drug products for:
- Conducting Periodic Quality reviews (Annual Product Review)
- Conducting Change Control that is documented, evaluated, approved and reviewed for re-validation needs
- Collection of reserve samples and review on an annual basis for possible product degradation
- Batch release

10. The labels of your outsourcing facility's compounded drug products do not include information required by section 503B(a)(10)(A). Specifically, the statements "This is a compounded drug", "Office Use Only", address and phone number of the outsourcing facility. Labels for the following compounded drug products do not contain these statements: Amiodarone 900mg in D5W 500mL, Nicardipine 25mg in 0.9% Sodium Chloride 250mL, Oxytocin 30 units in 0.9% Sodium Chloride 500mL and Norepinephrine 8mg in D5W 250mL. In addition, your outsourcing facility's drug product container labels do not contain the following information to facilitate adverse event reports: www.fda.gov/medwatch and 1-800-FDA-1088.

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