

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

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| DISTRICT ADDRESS AND PHONE NUMBER 555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax: (407) 475-4768 | DATE(S) OF INSPECTION 11/18/2019-12/10/2019* |
| | FEI NUMBER 3013023419 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
William Bruce Moorman, Staff Pharmacist

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| FIRM NAME BAYCARE INTEGRATED SERVICE CENTER | STREET ADDRESS 7802 E Telecom Pkwy |
| CITY, STATE, ZIP CODE, COUNTRY Temple Terrace, FL 33637-0928 | 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 I OBSERVED:

OBSERVATION 1

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

1.) A quality related event (QRE) was not documented for ephedrine sulfate 25 mg/5 ml for injection in pre-filled syringes lot (b) (4) indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia prepared on 7/25/2019 with a reported pH of 4.17 on 7/31/2019 by a contract test lab used for release testing. There was no investigation documented into a possible root cause for a pH lower than previously obtained through stability studies on (b) (4) lots prepared from 6/17-19/2019 with pH measurements ranging from (b) (4) to (b) (4) and pH specifications with upper and lower limits were not established. The contract test laboratory reported a pH of 6.84 on 7/29/2019; 6.87 on 8/8/2019; 7.00 on 8/8/2019; 6.85 on 8/8/2019; and 6.80 on 8/22/2019. 189 of these pre-filled syringes were released for patient use on 8/26/2019 after a contract laboratory investigation determined that the final pH was 6.8. 177 were distributed on 8/27/2019 for patient use with a beyond use date (BUD) of 45 days.

2.) A QRE report, which are a part of the investigations program, was not documented for ephedrine sulfate 25 mg/5 ml for injection in pre-filled syringes lot (b) (4) prepared on 8/22/2019 which was out of specification ((b) (4)) for potency at 91.3 %. The contract test laboratory also reported a pH result of 4.16 which is lower than previously obtained on (b) (4) batches of ephedrine sulfate 25 mg/5 ml for injection in pre-filled

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| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE Joanne E King, Investigator | Joanne E King Investigator Signed By: 1300174867 Date Signed: 12-10-2019 16:02:23 X _____ | DATE ISSUED 12/10/2019 |
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syringes prepared since 7/25/2019. The laboratory investigation covered the OOS for potency but did not include documentation on investigating the pH test result. This batch was rejected and destroyed on 9/4/2019, but no investigation was documented into a root cause for this out of specification potency result and a low pH result for which there were no established specifications.

3.) A QRE was not made for the oxytocin 30 units in 500 ml 0.9 % NaCl lot (b) (4) with the indication for use to induce uterine contractions (b) (4) time point stability study potency OOS (specifications of (b) (4)) with a reported 11.7 % on 8/14/2019. This batch was not for human use and not distributed according to batch record documentation, however no investigation was documented to indicate records reviewed by your QCU such as the (b) (4) weights for the oxytocin 30 units in 500 ml 0.9 % NaCl bags to determine a possible root cause.

OBSERVATION 2

The quality control unit lacks responsibility to approve and reject all procedures or specifications impacting on the identity, strength, quality and purity of drug products.

Specifically, you have not established upper and lower pH specifications for the following sterile drug products prepared by your firm since 7/25/2019:

- 1.) (b) (4) ephedrine sulfate 25 mg/5 ml in pre-filled syringes
- 2.) oxytocin 30 units in 500 ml NaCl 0.9% bags for injection
- 3.) vancomycin 1250 mg in 500 ml NaCl 0.9% bags for injection

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OBSERVATION 3

The responsibilities and procedures applicable to the quality control unit are not in writing.

Specifically, there is no written procedure for supplier and contract test lab qualifications. As an example, you have not assessed the compliance status of your contract test lab responsible for the control records and raw data to include release and stability testing for potency, endotoxin, sterility, and pH for all your sterile drug products.

OBSERVATION 4

Disinfectant contact time (also known as (b) (4) ") and coverage of the item being disinfected were insufficient to achieve adequate levels of disinfection.

Specifically, disinfection frequency and time are not specified and documented as evidence that they are applied consistently each time the sporicidal disinfectant is used.

- 1.) SOP P-305.4 *Cleaning and Disinfection of ISO Classified Controlled Environments and Rooms* did not include clear instructions or specifications on the use, frequency, and time sporicidal disinfectants are applied to the ISO 5 locations.
- 2.) SOP P-304.3 *Cleaning and Disinfection of Materials and Supplies in the Controlled Sterile Compounding Environment* did not include clear instructions on how the (b) (4) will be monitored.

OBSERVATION 5

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

Specifically, the air particle counter was not oriented in the direction of the horizontal first pass air when used to monitor particles in the (b) (4) laminar flow hood (b) (4) during the preparation of sterile drug products such as ephedrine 1000 mg q.s. with 200 ml in 0.9 % NaCl for injection lot (b) (4) and vancomycin 1250 mg in 500 ml 0.9 % NaCl for injection lot (b) (4) .

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***DATES OF INSPECTION**

11/18/2019(Mon), 11/19/2019(Tue), 11/20/2019(Wed), 11/21/2019(Thu), 11/22/2019(Fri),
11/27/2019(Wed), 12/05/2019(Thu), 12/06/2019(Fri), 12/10/2019(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."