DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA 4040 North Central Expressway Suite #300 Dallas, TX 75204 (214) 253-5200 Industry Information: www.fda.gov/oc/industry	11/27/17-12/22/17
	FEI NUMBER 3000717703

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Bruce W. Bagley, General Manager

FIRM NAME	STREET ADDRESS
Pharmedium Services, LLC	12620 West Airport Blvd. Suite #130
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Sugar Land, TX 77478	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:

OBSERVATION #1

The quality control unit lacks the responsibility and authority to reject all drug products. For example,

A. The product 0.2% Ropivacaine HCl in 0.9% Sodium Chloride for Injection,lot #171940195S (Production date: 7/14/17, Expiration date: 8/12/17) passed testing for endotoxin testing on 7/14/17 and was released for distribution. On 7/26/17, your firm discovered that lot #171940195S had failed testing for endotoxin and was later recalled.

B. The product Magnesium Sulfate 2 g 4 ml of 50% Injection) added to 100 ml 5% Dextrose Injection USP, lot #17033149S (Production date: 2/3/17 Expiration: 3/19/17) failed testing for endotoxin. The failure was attributed to the (b) (4) . The suitability of the (b) (4) was found acceptable, but in each case, the (b) (4) was re-tested using a new (b) (4) from the same lot with passing results. A nonconformance report was not issued.

Lot #17033149S was released for distribution.

C. The product Norepinephrine Bitartrate 1mg/ml 4ml in 5ml Ampule, lot #170330111S (Production date: 2/3/17 Expiration: 3/7/17) failed testing for endotoxin. The failure was attributed to the (b) (4) . The suitability of the (b) (4) was found acceptable, but in each case, the (b) (4) was re-tested using a new (b) (4) from the same lot with passing results. A nonconformance report was not issued.

Lot #170330111S was released for distribution.

OBSERVATION #2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Stephen D. Brown Jason R. Caballero	Stephen D. Brown, Investigator Dr. Jason R. Caballero, Investigator	12/22/2017

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA 4040 North Central Expressway Suite #300 Dallas, TX 75204 (214) 253-5200 Industry Information: www.fda.gov/oc/industry	11/27/17-12/22/17
	FEI NUMBER 3000717703

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Bruce W. Bagley, General Manager

FIRM NAME	STREET ADDRESS
Pharmedium Services, LLC	12620 West Airport Blvd. Suite #130
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Sugar Land, TX 77478	Outsourcing Facility

The flow of components, drug product containers, closures, labeling, in-process materials, drug products through the building is not designed to prevent contamination.

Specifically, a dynamic smoke study performed in 3/17 revealed the ingress of air from the unclassified staging area into the ISO 7 Pass In area when the door was open. Your firm performed a "(b) (4) " of the differential pressure which, to date, has not been verified (deadline 12/31/17). In addition, smoke studies have not been conducted to verify that the "(b) (4) " of air pressure resolved the issue. Prior to 3/17, dynamic smoke studies evaluating the flow of air between unclassified and classified areas have never been conducted.

OBSERVATION #3

Your firm failed to establish and follow appropriate written procedures that are designed to prevent microbiological contamination of drug products purporting to be sterile.

Specifically,

A. On 11/27/17, I (CSO Brown) observed that several technicians engaged in aseptic processing did not consistently re-sanitize their gloves to include the wrist after moving from the ISO 7 area to the ISO 5 hood. In addition, technicians failed to sanitize their gloved hands after transferring plastic bags containing tube sets to the ISO 5 hoods.

B. On 12/12/2017, I (CSO Caballero) observed the firm's compounding technician handle non-sterile paperwork in the cleanroom area and immediately proceed to compound drug product, 1.5 g Vancomycin HCL in 0.9% Sodium Chloride, Lot # 173450110S, (b) (4) , inside the firm's ISO5 hood (b) (4) without sanitizing her hands with sterile (b) (4)

OBSERVATION #4

There is a failure to thoroughly investigate any unexplained discrepancy or failure of a batch , regardless of whether the batch has been distributed, or a failure to expand an investigation to assess other batches that may also be impacted.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Stephen D. Brown Jason R. Caballero	Stephen D. Brown, Investigator Dr. Jason R. Caballero, Investigator	12/22/2017

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA 4040 North Central Expressway Suite #300 Dallas, TX 75204 (214) 253-5200 Industry Information: www.fda.gov/oc/industry	11/27/17-12/22/17
	FEI NUMBER 3000717703

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Bruce W. Bagley, General Manager

FIRM NAME	STREET ADDRESS
Pharmedium Services, LLC	12620 West Airport Blvd. Suite #130
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Sugar Land, TX 77478	Outsourcing Facility

A. Sterility Testing

Review of sterility failures in 2017 revealed that the investigations were incomplete in that: 1) the contaminating microorganism was not identified , and 2) there was no assessment of other lots from the same ISO 5 hood which may have been affected. In each case, the lots were not distributed. For example,

1. Nonconformance #SNC-17-975 dated 11/29/17 documents that "Ropivacaine HCl in 0.9% Sodium Chloride Injection Pumps, lot numbers 172120168S, 172120156S, 172120172S, and 172120183S failed sterility testing on 3/1/17. The investigation does not include an assessment of the need for additional sampling of other products or increased environmental monitoring to determine potential impact.

The related laboratory investigation #SL-2017-003 dated 8/1/17 (QM approval date) documents that no laboratory error occurred during the investigation.

2. Nonconformance #SNC-17-136 dated 10/30/17 documents that 0.2% Ropivacaine HCl in 0.9% Sodium Chloride in On Q Pump, lot numbers 170320090S and 170320098S, failed sterility testing on 2/2/17. The investigation does not include an assessment of the need for additional sampling of other products or increased environmental monitoring to determine potential impact.

The related laboratory investigation #SL-2017-001 dated 2/15/17 (QM approval date) documents that no laboratory error occurred during the investigation.

B. Endotoxin Testing

The product 0.5% Ropivacaine HCl 30 ml Total Volume in a 30 ml BD syringe, lot # 170690291S failed testing for endotoxin on 3/13/17 (Result: 0.475 EU/ml, Endotoxin limit (b) (4) EU/ml). The lot was re-tested with passing results but was not distributed. A root cause was not determined.

Since 1/17, your firm has issued Nonconformance Forms for 8 additional lots of drug product which failed to meet specifications for endotoxin. In each case, the product was discarded. However, the investigations remain open.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Stephen D. Brown Jason R. Caballero	Stephen D. Brown, Investigator Dr. Jason R. Caballero, Investigator	12/22/2017

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA 4040 North Central Expressway Suite #300 Dallas, TX 75204 (214) 253-5200 Industry Information: www.fda.gov/oc/industry	11/27/17-12/22/17
	FEI NUMBER 3000717703

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Bruce W. Bagley, General Manager

FIRM NAME	STREET ADDRESS
Pharmedium Services, LLC	12620 West Airport Blvd. Suite #130
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Sugar Land, TX 77478	Outsourcing Facility

Some examples consist of the following:

A. SNC-17-409 dated 3/24/17 (0.25% Ropivacaine in 0.9% Sodium Chloride, lot #170820130S)
B. SNC-17-1607 dated 4/27/17 (Ropivacaine HCl 0.5%, lot #171160125S)
C. SNC-17-1456 dated 9/22/17 (0.2% Ropivacaine HCl in 0.9% Sodium Chloride 750 ml, lot #172640207S)
D. SNC-17-1457 dated 9/25/17 (100mg/ml Cefazolin Sodium 2 g in Sterile Water for Injection USP, lot #172650138S)

C. Environmental Monitoring

Since 1/2017, your firm has had over 100 microbial excursions at action level in the ISO 5 hoods for air, surface, and personnel samples. Your firm performed an investigation which concluded that the source of the contamination (i.e. Aspergillis species) was confined to media fill bags obtained from a vendor. However, corrective action has not been implemented. Some examples consist of the following:

1. An "Over the Action Investigation Report" dated 9/21/17 documented that Aspergillis creber and Penicillium decumbens were isolated in routine EM samples in Hood #(b) (4) There was no investigation. A total of (b) (4) lots were produced in Hood #(b) (4) on 9/21/17 and distributed to consignees.

2. An "Over the Action Investigation Report" dated 9/27/17 documented that Aspergillis creber was isolated in routine EM samples in Hood #(b) (4) There was no investigation. A total of (b) (4) lots were produced in hood #(b) (4) on 9/27/17 and distributed to consignees.

D. Potency

From 1/2017 to the present, your firm reported a total of 289 confirmed OOS results for potency. Review of the "Investigation Report Assignment Log" for 2017 revealed that there was no documentation that the investigations had been closed. However, an investigation into the root cause has not been completed for approximately (b) (4) lots of drug products. For example, the following nonconformance investigations remain open:

1. SNC17-1548 dated 11/22/17 for Heparin, lot #173210103S

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Stephen D. Brown Jason R. Caballero	Stephen D. Brown, Investigator Dr. Jason R. Caballero, Investigator	12/22/2017

2. SNC-17-1213 dated 9/12/17 for Epinephrine HCl 20mcg/ml 200mcg/10ml, lot #172500010S
3. SNC-17-150 dated 1/25/17 for Oxytocin 20 Units added to 1000ml 5% Dextrose, lot #170230175S

In addition, review of OOS investigations for potency revealed that your firm failed to substantiate the invalidation of OOS results. Some examples consist of the following:

a. Investigation #17-EPA-546 dated 11/30/17 documented that Oxytocin, lot #173250058S failed testing for potency with a value of 33.70 U (Specification (b) (4) - (b) (4) U). Subsequent re-testing passed. The reason for the invalidation of the original OOS result was a "possible bad injection" which was not verified. The lot was distributed.

b. Investigation #17-EPA-544 dated 12/4/17 documented that Phenylephrine HCl 20 mg added to 250 ml 0.9% Sodium Chloride Injection USP, lot #173250080S failed testing for potency three times: (b) (4) (b) (4) . Subsequent testing of a new sample passed specifications and was released. The conclusion was that "The original preparation was either pipetted wrong or not mixed well and it should be invalid." There was no scientific rationale for this conclusion. The lot was distributed.

c. Investigation #17-EPA-543 dated 11/28/17 documented that Lidocaine HCl 2% 20mg/ml 60 mg/3 ml, lot #173220027M failed testing for potency five times: (b) (4) (b) (4) Subsequent testing of a new preparation of the same sample passed specifications and was released. The conclusion was that "The original was prepared wrong probably with a dilution error and should be invalid." There was no scientific rationale for this conclusion. The lot was distributed.

E. Investigation of recalls

Your firm failed to complete investigations, corrective actions/preventative actions, and root cause analysis, health hazard analyses, recall file checklists, and recall initiation checklists, when handling the following recalls:

• RE-017-002: Products: 0.2% Ropivacaine HCL in 0.9% Sodium Chloride and 0.25% Bupivacaine HCL in 0.9%

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA 4040 North Central Expressway Suite #300 Dallas, TX 75204 (214) 253-5200 Industry Information: www.fda.gov/oc/industry	11/27/17-12/22/17
	FEI NUMBER 3000717703

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Bruce W. Bagley, General Manager

FIRM NAME	STREET ADDRESS
Pharmedium Services, LLC	12620 West Airport Blvd. Suite #130
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Sugar Land, TX 77478	Outsourcing Facility

Sodium Chloride, ten lots affected.
• RE-017-003: Products: 1.5 g Vancomycin HCL in 5% Dextrose 300mL in 500mL Intravenous Bag, 7mMol Potassium Phosphate in 0.9% Sodium Chloride 100mL in 150mL Intravenous Bag, sixty-five lots affected .
• RE-017-005 Product: 1.25 g Vancomycin HCL added to 5% Dextrose Injection USP 250 mL in 250 mL Viaflex Bag, one lot affected.
• RE-017-007 Product: 9% Buffered Lidocaine HCL (buffered in 8.4% Sodium Bicarbonate) 5 mL in 5 mL BD Syringe, twelve lots affected.

OBSERVATION #5

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically, review of hood certifications for the period between 1/2017 and the present revealed that in at least two cases the vendor responsible for certification documented a HEPA failure (leakage) which was repaired. However, in each case, your firm failed to determine the impact of the leakage on lots of drug products produced in the respective hoods before the failures occurred.

OBSERVATION #6

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

A. Review of disinfectant effectiveness studies revealed multiple failures utilizing disinfectants currently in use. An investigation to determine the root cause was not conducted.

B. Your firm is using non-sterile (b) (4) with sterile (b) (4) which are combined to disinfect bag ports and vial tops. The components are prepared in an unclassified area.

C. SOP #CPS-301 entitled, "Facility Cleaning" (Effective date: 5/221/7) establishes a (b) (4) minute contact time for the disinfectants used in the facility. The suppliers of the disinfectants recommend a (b) (4) minute contact time.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Stephen D. Brown Jason R. Caballero	Stephen D. Brown, Investigator Dr. Jason R. Caballero, Investigator	12/22/2017

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA 4040 North Central Expressway Suite #300 Dallas, TX 75204 (214) 253-5200 Industry Information: www.fda.gov/oc/industry	11/27/17-12/22/17
	FEI NUMBER 3000717703

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Bruce W. Bagley, General Manager

FIRM NAME	STREET ADDRESS
Pharmedium Services, LLC	12620 West Airport Blvd. Suite #130
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Sugar Land, TX 77478	Outsourcing Facility

Environmental monitoring isolates obtained from the ISO 5 hoods in the last 6 months have revealed the presence of Aspergillus, Cladosporium, and Rhizopus.

THIS IS A REPEAT OBSERVATION

OBSERVATION #7

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

Specifically, environmental monitoring for non-viable particulates (air) is not performed at sufficient frequencies to represent routine production conditions within the IS0-7 Clean Room or the IS0-5 (b) (4) Laminar Air Flow Hoods. Currently, your firm performs non-viable monitoring of the ISO 5 hoods on a (b) (4) basis.

OBSERVATION #8

Procedures designed to prevent microbiological contamination of sterile drug products does not include adequate validation of aseptic processing.

Specifically, process simulations are deficient in that new operators are not required to complete media fills for specific sub-processes (i.e. (b) (4) before being released to production.

OBSERVATION #9

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that components, in-process materials and drug products conform to appropriate standards of identity, strength, quality , and purity.

Specifically, the visual inspection of finished sterile drug products for particulate matter is not performed against a (b) (4) for visualization of various types of particles throughout the filled container. Your firm approved SOP #CPS-788 entitled, "Visual Inspection" (Approval date: 3/21/17) which includes provision for

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Stephen D. Brown Jason R. Caballero	Stephen D. Brown, Investigator Dr. Jason R. Caballero, Investigator	12/22/2017

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA 4040 North Central Expressway Suite #300 Dallas, TX 75204 (214) 253-5200 Industry Information: www.fda.gov/oc/industry	11/27/17-12/22/17
	FEI NUMBER 3000717703

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Bruce W. Bagley, General Manager

FIRM NAME	STREET ADDRESS
Pharmedium Services, LLC	12620 West Airport Blvd. Suite #130
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Sugar Land, TX 77478	Outsourcing Facility

inspection using a (b) (4) . However, the SOP has not been implemented.

OBSERVATION #10

Samples taken of drug products for determination of conformance to written specifications are not representative.

Regardless of batch size, (b) (4) for sterility and endotoxin testing of all batches, unless the finished dosage unit contains less than (b) (4), in which (b) (4) are pulled. For example:

A. Oxytocin 20 Units added to 500 ml 0.9% Sodium Chloride Injection, USP, lot #170200098S (Sample: (b) (4) (b) (4))

B. Magnesium Sulfate 2 g (4 ml of 50% Injection) added to 100 ml 5% Dextrose Injection USP 1 , lot #170330149S (Sample: (b) (4))

C. 0.2% Ropivacaine HCl in 0.9% Sodium Chloride Injection 400ml in 400ml On Q Fixed Primed, lot #171940195S (Sample: (b) (4))

OBSERVATION #11

Input to and output from the computer, related systems of formulas, records or data are not checked for accuracy.

A. Your firm has no procedure to describe the review of analytical data used for release testing of finished drug products. There is no documented review of electronic raw data or audit trails, to determine, for example, whether product has undergone unauthorized retesting or whether data has been otherwise manipulated. Testing for potency , sterility , and endotoxin is performed on all finished product batches, and all of the testing equipment captures data electronically (e.g. (b) (4)
(b) (4)
(b) (4) System for endotoxin analysis, and (b) (4) System).
SOP CPS-728, Review of Batch Processing Documentation, does not describe any review of analytical data.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Stephen D. Brown, Investigator Dr. Jason R. Caballero, Investigator	12/22/2017

B. Quality Control laboratory worksheets are issued from an electronic document control system, but are accessible to the analyst for unlimited printing , with no date/time-stamp or other issuance controls for reconciliation against other laboratory data.

C. Electronic logs of Quality System reports or files are maintained on uncontrolled spreadsheets on a shared network drive, and there are no controlled paper logs. The electronic spreadsheets do not have an audit trail function to show if previously entered items have been altered or deleted. Logs for the following items are stored in this manner: Notice of Event (NOE) reports, Non-Conformance Reports (NCRs), Laboratory Out-Of-Limit or Out-Of-Specification (OOLIOOS) reports, and and Corrective and Preventive Action (CAPA) reports.

OBSERVATION #12

1. 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:
a) The date that the drug was compounded.
b) A list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient.
Examples of drug product labels that do not contain this information include:
• Oxytocin 30 units added to 500 mL 0.9% Sodium Chloride Injection USP (503 mL total volume)
• NORepinephrine Bitartrate 4 mg added to 250 mL 0.9% Sodium Chloride Injection USP (16 mcg per mL) (254.00 mL total volume)
• EPINEPHrine HCl 4 mg added to 250 mL 5% Dextrose Injection USP (16 mcg per mL) (254.00 mL total volume)
• Magnesium Sulfate 2 g (4 mL of 50% Injection) added to 50 mL 0.9% Sodium Chloride Injection USP (54.00 mL total volume)
• Diltiazem HCl 125 mg in 125 mL 0.9% Sodium Chloride Injection USP (1 mg per mL)
• Calcium GLUCOnate 1 g (10 mg per mL) in Dextrose 5% (100 mL total volume in a 150 mL Intravia bag)
• 0.2% Ropivacaine HCl in 0.9% Sodium Chloride (60 mL total volume in 60 mL BD Syringe)

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA 4040 North Central Expressway Suite #300 Dallas, TX 75204 (214) 253-5200 Industry Information: www.fda.gov/oc/industry	11/27/17-12/22/17
	FEI NUMBER 3000717703

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Bruce W. Bagley, General Manager

FIRM NAME	STREET ADDRESS
Pharmedium Services, LLC	12620 West Airport Blvd. Suite #130
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Sugar Land, TX 77478	Outsourcing Facility

• PHENYLephrine HCl 20 mg added to 250 mL 0.9% Sodium Chloride Injection USP (80 mcg per mL) (252.00 mL total volume)
• Heparin Sodium Injection USP 25,000 USP Units added to 250 mL 0.9% Sodium Chloride Injection USP (100 units per mL) (255.00 mL total volume)
• Vasopressin 50 units added to 50 mL 0.9% Sodium Chloride Injection USP (1 unit per mL) (52.50 mL total volume)
• Sodium PHOSphate added to 0.9% Sodium Chloride 15 mMol 250 mL bag (255.00 mL total volume)
• Oxytocin 20 units added to 1000 mL 0.9% Sodium Chloride Injection USP (1002.00 mL total volume)
• Oxytocin 40 units added to 1000 mL 0.9% Sodium Chloride Injection USP (1004.00 mL total volume)
• Magnesium Sulfate 2 g (4 mL of 50% Injection) added to 50 mL 5% Dextrose Injection USP (54.00 mL total volume)
• 0.25% Bupivacaine HCl in 0.9% Sodium Chloride Injection (500 mL total volume in an ON-Q Pump)

THIS IS A REPEAT OBSERVATION

OBSERVATION #13

Your outsourcing facility has not submitted a report to FDA identifying a product compounded during the December 1, 2016, through May 31, 2017, reporting period as required by section 503B(b)(2)(A). Specifically, the following products were compounded and not identified on your June 2017 report:

• 10 mEq Potassium Chloride and 10 mg Lidocaine added to 0.9% Sodium Chloride
• 20 mEq Potassium Chloride and 10 mg Lidocaine added to 5% Dextrose

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Stephen D. Brown Jason R. Caballero	Stephen D. Brown, Investigator Dr. Jason R. Caballero, Investigator	12/22/2017