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	2/12-16, 3/12 -13/2018 FEI NUMBER 3013927023

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mr. Jarred D.Dudding, Pharmacist in Charge

FIRM NAME	STREET ADDRESS
Apollo Care LLC	3801 Mojave Court Suite 101
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Columbia, MO 65202	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 no Quality Control Unit.

Specifically,

A. You failed to establish a quality control unit with the responsibility and authority to approve or reject all procedures or specifications impacting on the identity, strength, quality and purity of the drug product.

B. The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed, as:

1. There is no SOP for complaint review, documentation, investigation and corrective and preventive actions to be performed.
2. Your SOP no. CQ1006.1 Good Documenting Practices" is not followed as you do not ensure corrections with product batch records are made by drawing a single line through the information to be corrected, you do not initial with the personnel making the correction and date, and you do not include comments on the corrected or new entry.
3. There are no SOPs related to your labeling activities and there are no Master Labels maintained.
4. Your SOPs are not complete and accurate as you refer to other SOPs in your procedures which you include as "SOP XXX" or "SOP ???". Examples of this can be found in the following SOPs:
   - SOP no. CQ1003.1 "Clean Room Monitoring on pages 1 and 4.
   - SOP no. EMP011.1 "Gloved Fingertip Sampling Performance Measurement" on page 3.

SEE REVERSE OF THIS PAGE	Michele Perry-Williams, Investigator	X	3/13/2018

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	2/12-16, 3/12 -13/2018 FEI NUMBER 3013927023

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Jarred D.Dudding, Pharmacist in Charge

FIRM NAME	STREET ADDRESS
Apollo Care LLC	3801 Mojave Court Suite 101
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Columbia, MO 65202	Outsourcing Facility

C. Drug product component testing is deficient in that at least one specific test to verify the identity of each component is not performed. You receive material for production without a Certificate of Analysis (i.e. COA) and use this material in your sterile processing operations without the receipt and review of a Certificate of Analysis and no additional testing or evaluation is performed. Examples of this practice is with your 0.9% Sodium Chloride Injection, USP used to manufacture your Vancomycin sterile injectable product. This is also your practice with the Sterile Water for Injection which is used in both your Vancomycin in 0.9% Sodium Chloride and Sodium Bicarbonate sterile prepared products.

D. SOP no. INST001.1 "Performing Visual Inspection – Sterile Practices" includes information to examine preparations against a matte black background and against a non-glare white background using an incandescent light. Currently you use the white background in the Storage Room 1 to look at the product by holding the bag up, turning it over to look for particulates. There is no black background used and there is no documentation of this review.

E. After operations have been completed, there is no Quality Unit review of the processing records before the product is distributed.

OBSERVATION 2

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

Specifically,

You did not conduct an investigation into the stability failure of your Vancomycin HCL 500 mg in 250mL of 0.9% Sodium Chloride Inj. Product after receiving out of specification test results at day (b) (4) for potency which did

SEE REVERSE OF THIS PAGE	Michele Perry-Williams, Investigator	X	3/13/2018

not support your BUD of 90 days for this product. You continued to manufacture and distribute Vancomycin HCL 1g in 250mL of 0.9% Sodium Chloride and Vancomycin HCL 1.25g in 250mL of 0.9% Sodium Chloride Injection products which were affected by this stability failure after the stability failure of the Vancomycin HCL 500 mg in 250mL of 0.9% Sodium Chloride product occurred.

1. You recorded environmental monitoring results on the following dates which exceeded your alert and/or action limits but you failed to conduct an investigation and/or initiate any corrective or preventive actions:

Date	Product/Lot no.	Location	Alert Limit	Action Limit	Results
11/14/17	(b) (4)	(b) (4) Plates -Anteroom (b) (4)	(b) (4	(b) (4)	5
11/4/17	(b) (4)	(b) (4) Plates – Anteroom	(b) (4	(b) (4)	5
11/4/17	(b) (4)	Left Sleeve	(b) (4	(b) (4)	7
10/17/17	(b) (4)	(b) (4) Plates -Anteroom (b) (4)	(b) (4	(b) (4	3
10/17/17	(b) (4)	(b) (4) Plates – Anteroom	(b) (4	(b) (4)	13

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	2/12-16, 3/12 -13/2018 FEI NUMBER 3013927023

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Jarred D.Dudding, Pharmacist in Charge

FIRM NAME	STREET ADDRESS
Apollo Care LLC	3801 Mojave Court Suite 101
CITY, STATE, ZIP CODE, COUNTRY Columbia, MO 65202	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

OBSERVATION 3

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

Specifically, there are no documented training records prior to 1/9/18 for your personnel who were involved in processing operations of (b)(4) lots of sterile injectable product between 10/17/17 and 1/9/18. This includes distributed products Vancomycin 1250 mg in 250 mL of 0.9% Sodium Chloride lot (b) (4) and 8.4% Sodium Bicarbonate Injection 50 mEq (1mEq/mL) 50 mL Syringe lot (b) (4) .

OBSERVATION 4

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established or followed:

Specifically,

A. Aseptic operators are not initially qualified by performing at least one (1) successful media fill run before starting production.
B. The smoke study is deficient as it was only performed for (b) (4) in each ISO-5 areas. The smoke study was not conducted while simulating your current manufacturing and operating processes.
C. The media fill performed is inadequate as it does not simulate the complete sterile operations for the products currently being processed and distributed as follows:

SEE REVERSE OF THIS PAGE	Michele Perry-Williams, Investigator	x	3/13/2018

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	2/12-16, 3/12 -13/2018 FEI NUMBER 3013927023
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mr. Jarred D.Dudding, Pharmacist in Charge	
FIRM NAME Apollo Care LLC	STREET ADDRESS 3801 Mojave Court Suite 101
CITY, STATE, ZIP CODE, COUNTRY Columbia, MO 65202	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

1. For Vancomycin Injection, your process media fill demonstration failed to include processing operations when you add the aseptically filled Vancomycin stock solution into the 250mL 0.9% Sodium Chloride IV bags, which is your finished product. Your media fill simulation has also not demonstrated the worst case manufacturing operations for this product.
2. For Sodium Bicarbonate Injection, your medial fill demonstration failed to include processing operations when you transfer the 8.4% Sodium Bicarbonate Stock Solution into the 60mL (b) (4) Syringes. Your media fill simulation has also not demonstrated the worst case manufacturing operations for this product.

D. During your room qualification activities, your HEPA filters were found to have leaks in the following ISO-7 areas:
   - Lab(b)(4) HEPA Filter (b) (4) which was documented in the September 18, 2017 Controlled Environment Certification Report #: GF09181701. You continued sterile operations of at least(b)(4) compounded lots of product before having the HEPA filter replaced.
   - Lab(b)(4) HEPA Filter no.(b) (4) and HEPA Filter (b) (4) which was documented in the January 22, 2018 Controlled Environment Certification Report #: RK01221801. You continued sterile operations of at least 1 compounded lot of product before having the HEPA filter replaced.

E. After the HEPA filters were replaced, which you document with Invoice Reports only, you have continued your processing operations without recertifying these areas. They include:
   - Lab(b)(4) also known as (b) (4) Lab (b)(4) where aseptic filling operations occur.
   - Lab(b)(4) (also known as Product Finishing Lab(b)(4) where finished product processing operations occur.

F. On 2/14/18, I observed your cleaning practice and found you do not follow your SOP no. PRC002.1 "Controlled 'Environment Cleaning Procedure". You failed to use aseptic cleaning

techniques as you do not use overlapping stokes, you do not clean from the inside out, or from the top, downward, when cleaning the ISO-5 Hood.

G. In your SOP for gowning no. EMP006.1 "Donning Personal Protective Equipment – Aseptic Techniques" there are instructions to "avoid touching the outside of the body suit (i.e. the part that will come in contact with the environment). I observed gowning on 2/13/18 and 2/14/18 and found your gowning technique was inadequate as the operators' gown touch the floor and the operator continued to gown to enter the compounding suites.

H. In your environmental monitoring program in accordance to your SOP no. CQ1003.1 "Clean Room Monitoring" you do not perform environmental monitoring on all equipment located in your ISO 5 and IS0 7 areas as follows: Sharp Containers designed for needle disposal located inside of the ISO 5 area, all carts and shelves located in the ISO 7 area.

I. You perform mixing and weighing operations of raw materials used to manufacture your Vancomycin and Sodium Bicarbonate products in a non-classified area and not in at least an ISO 8 area.

OBSERVATION 5

The batch production and control records are deficient in that they are not an accurate reproduction of the appropriate master production or control record and are not checked for accuracy, dated, and signed.

Specifically,

1. You do not have Master Batch Records for the sterile drug products currently being manufactured and distributed. The batch production and control records are deficient in that they do not include specific identification of each batch of component used.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	2/12-16, 3/12 -13/2018
	FEI NUMBER 3013927023

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mr. Jarred D.Dudding, Pharmacist in Charge	
FIRM NAME Apollo Care LLC	STREET ADDRESS 3801 Mojave Court Suite 101
CITY, STATE, ZIP CODE, COUNTRY Columbia, MO 65202	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

2. You failed to include the correct information in the finished product record for the lots of stock solutions used to produce the sterile product. This error was performed in all the prepared lots you have manufactured and distributed. This information also includes the incorrect expiration date of the stock solutions recorded in your finished product batch records. The lot number information for your stock solution batches is also not recorded on the stock solution batches records.

3. In your Vancomycin Batch Records, you do not include the lot number and expiration date information for the Sodium Chloride Injection product used during sterile operations.

4. You do not include the lot number information for sterile water for injectable used to manufacture your stock solution in your stock solution batch records.
5. The batch records for your sterile drug products reference SOPs. In your batch records you do not include the SOP number being referenced, but use "XXX". This is included in the following:

   A. 8.4% Sodium Bicarbonate Injection 50mEq (1 mEq/mL) 50 mL Syringe batch record for lot no. (b) (4) , prepared on 11/9/17, under the "Preparation" Section B, includes information on two (2) SOPs which both include "XXX" instead of the SOP number being referenced.
   B. Vancomycin 1250 mg in 250 mL of 0.9% Sodium Chloride batch record lot (b) (4) prepared on 12/14/17, under the "Preparation" Section B includes information on two (2) SOPs which both include "XXX" instead of the SOP number being referenced.

6. In the Stock Solution Batch Records for Vancomycin you do not include the "Technicians' Signature" perform operations Listed under "STERILE WATER" and/or NA, sign and date this space.

SEE REVERSE OF THIS PAGE	Michele Perry-Williams, Investigator	X	3/13/2018

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	2/12-16, 3/12 -13/2018
	FEI NUMBER 3013927023

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mr. Jarred D.Dudding, Pharmacist in Charge	
FIRM NAME Apollo Care LLC	STREET ADDRESS 3801 Mojave Court Suite 101
CITY, STATE, ZIP CODE, COUNTRY Columbia, MO 65202	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

OBSERVATION 6

Routine calibration, inspection of mechanical and electronic equipment is not performed according to a written program designed to assure proper performance.

Specifically, there is no calibration and maintenance SOP and no calibration and maintenance program. The following pieces of equipment used during processing or storage operations, do not have calibration documentation and activities performed; and have not been included in any type of schedule to assure calibration is performed:

- (b) (4) scale used to weigh ingredients included in the formulation for sterile injectable products.
- (b) (4) used to depyrogenate glass beakers. There is no SOP which describes the (b) (4) depyrogenation cycle and there has been no effectiveness evaluation of the (b) (4) dehydrogenation cycle to verify the cycle is capable of achieving a 3-log reduction in endotoxin. In addition, you have not conducted qualification activities including temperature mapping of this unit.
- Refrigerator containing the Vancomycin Finished Product is set at (b) (4) C. You have not conducted qualification activities including temperature mapping of this unit.
- Incubator asset no. (b) (4) used to incubate environmental monitoring plates has not been calibrated and no qualification activities have been performed.

SEE REVERSE OF THIS PAGE	Michele Perry-Williams, Investigator	X	3/13/2018

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	2/12-16, 3/12 -13/2018 FEI NUMBER 3013927023

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mr. Jarred D.Dudding, Pharmacist in Charge	
FIRM NAME Apollo Care LLC	STREET ADDRESS 3801 Mojave Court Suite 101
CITY, STATE, ZIP CODE, COUNTRY Columbia, MO 65202	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

OBSERVATION 7

Aseptic processing areas are deficient in that floors and walls are not smooth and/or hard surfaces that are easily cleanable.

Specifically, the surfaces in the classified areas were not easily cleanable as the following was observed:

- The ISO-5 hood asset no. (b) (4) located in the (b) (4) Lab(b) (4) has a crack on the left side of the front of the Formica counter top which is a part of the working surface located in the ISO-5 area. (b) (4) Lab(b) (4)s the area where aseptic filling operations occur which has(b) (4) ISO-5 Hoods (b) (4)

- The working surface inside of the ISO-5 Hood, asset no (b) (4), has a crack in the front of the counter top and a piece of the Formica counter top is missing. This Laminar Flow Hood is in the Product Finishing Lab(b) (4) which is where finished product operations occur for your sterile filled products. This Lab has(b) (4) ISO-5 Hoods (b) (4)
- There was dirt/debris located on the tops of all your (b) (4) laminar flow hoods.
- There was paint chipped off the door in ISO-7 area located in Finishing Lab(b) (4)
- There was a rust stain and scratches located on the door frame in (b) (4) Lab(b) (4) where the aseptic sterilizing process occurs for your Vancomycin and Sodium Bicarbonate sterile products.
- The power poles were not sealed at the bottom which are in all(b) (4) Labs where sterile processing operations occur for your sterile injectable products. These poles include additional electrical outlets for your operations.

SEE REVERSE OF THIS PAGE	Michele Perry-Williams, Investigator	X	3/13/2018

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	2/12-16, 3/12 -13/2018 FEI NUMBER 3013927023

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mr. Jarred D.Dudding, Pharmacist in Charge	
FIRM NAME Apollo Care LLC	STREET ADDRESS 3801 Mojave Court Suite 101
CITY, STATE, ZIP CODE, COUNTRY Columbia, MO 65202	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

OBSERVATION 8

Each lot of components was not appropriately identified as to its status in terms of being quarantined, approved or rejected.

Specifically,

Product which was said to be Quarantined for return to the manufacturer (b) (4) cases of Sodium Chloride Inj. Lot no. (b) (4) to be used in Vancomycin and (b) (4) cases of Lactated Ringer Inj. Lot no. (b) (4) to be used in Oxytocin) was not labeled, segregated and/or isolated. This product which you stated was damaged upon delivery was not labeled "Quarantined or the be Returned" and was located next to materials to be used during the productions of your sterile injectable products.

OBSERVATION 9

Bagged or boxed components of drug product containers are not stored off the floor and suitably spaced to allow cleaning and inspection.

Specifically,

On 2/12/18, we observed (b) (4) cases of materials to be used during production (Sodium Chloride 0.9% for Injection and Lactated Ringers for Injection) which were stored directly on the floor in the warehouse area.

SEE REVERSE OF THIS PAGE	Michele Perry-Williams, Investigator		3/13/2018

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	2/12-16, 3/12 -13/2018 FEI NUMBER 3013927023

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mr. Jarred D.Dudding, Pharmacist in Charge	
FIRM NAME Apollo Care LLC	STREET ADDRESS 3801 Mojave Court Suite 101
CITY, STATE, ZIP CODE, COUNTRY Columbia, MO 65202	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

In addition, some of this product contained temperature storage room temperature and you do not monitor temperature in this area. I observed a lot of Sodium Chloride, lot no. (b) (4), with temperature storage requirements of (b) (4)-(b) (4) °C included on the labels.

OBSERVATION 10

Drug product component testing is deficient in that at least one specific test to verify the identity of each component is not performed.

Specifically, you receive raw materials without a Certificate of Analysis (i.e. COA) and use raw materials in your sterile processing operations without the receipt and review of a Certificate of Analysis and no additional testing or evaluation is performed. Examples of this practice is with your 0.9% Sodium Chloride Injection, USP raw material used to manufacture your Vancomycin sterile injectable product. This is also your practice with the Sterile Water for Injection which is used in both your Vancomycin in 0.9% Sodium Chloride and Sodium Bicarbonate sterile prepared products.

OBSERVATION 11

Batch production and control records do not include results of examinations made of packaged and labeled products for correct labeling.

Specifically, there is no documented review of the labels during packaging and after the labeling and packaging operations occur.

SEE REVERSE OF THIS PAGE	Michele Perry-Williams, Investigator	X	3/13/2018

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	2/12-16, 3/12 -13/2018 FEI NUMBER 3013927023

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mr. Jarred D.Dudding, Pharmacist in Charge

FIRM NAME	STREET ADDRESS
Apollo Care LLC	3801 Mojave Court Suite 101
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Columbia, MO 65202	Outsourcing Facility

OBSERVATION 12

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

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 your drug product labels:

- The date that the drug was compounded;
- Storage and handling instructions; and
- A list of active and inactive ingredients (sterile water for injection), identified by established name and the quantity or proportion of each ingredient

Examples of drug products labels that do not contain this information:

- 8.4% Sodium Bicarbonate (1mEq/mL) 50mL Syringe
- Vancomycin 750mg added to 250ml of 0.9% Sodium Chloride
- Vancomycin 1g added to 250ml of 0.9% Sodium Chloride
- Vancomycin 1.25g added to 250ml of 0.9% Sodium Chloride
- Vancomycin 1.5g added to 250ml of 0.9% Sodium Chloride
- Vancomycin 1.75g added to 500ml of 0.9% Sodium Chloride
- Vancomycin 2g added to 500ml of 0.9% Sodium Chloride

SEE REVERSE OF THIS PAGE	Michele Perry-Williams, Investigator	X	3/13/2018