

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

DISTRICT ADDRESS AND PHONE NUMBER 4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax: (214)253-5314	DATE(S) OF INSPECTION 4/2/2018-4/20/2018* FEI NUMBER 3012669715
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Jack R. Munn, Owner

FIRM NAME Guardian Pharmacy Services	STREET ADDRESS 7920 Elmbrook Dr Ste 108
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CITY, STATE, ZIP CODE, COUNTRY Dallas, TX 75247-4933	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drug Products
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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

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

Specifically,


1. SOP 3.030, "Environmental Monitoring of the Clean Room Facility, ver. 2.0., eff. 2/1/2013 which establishes the type and frequency of personnel and surface monitoring within your classified cleanroom environments require personnel sampling and ISO 5 surface sampling at least once a month upon (b) (4). However, neither sampling has been conducted since December 28, 2017. The infrequency of environmental and personnel monitoring is a **repeat observation**.

2. Semi-annual recertification services of the ISO 5 laminar air flow hoods, ISO 7 buffer room, and ISO 8 anteroom contracted with *AirScanTech*, has not been performed since 6/28/2017.

OBSERVATION 2

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

AMENDMENT 1

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Specifically,

1. The current cleaning procedure, SOP 3.020, "Cleaning and Maintenance of the Clean Room Facility, version 2.0. eff. 2/15/03", section 8.1.2, states that "all IPA designated for use in the clean room facility must be sterile". However, nonsterile 70% Isopropyl Alcohol is used to sanitize surfaces within the ISO 5 laminar air flow bench where aseptic processing of drug products occur, as well as within other areas within the ISO 7 buffer room and ISO 8 anteroom.
2. Non-sterile plastic dispensers labeled as containing "Sterile IPA" was observed being used to sanitize the inner surfaces of the ISO 5 laminar airflow workbenches, processing materials, surfaces within the ISO 7 buffer room and ISO 8 anteroom, and to sanitize sterile gloves worn by the sterile operator. However, the bulk container of isopropyl alcohol was observed non-sterile. In addition, these plastic dispensers are indefinitely reused without cleaning and sanitizing between use.
3. The current cleaning regime, as stated by the sterile operator (b) (6) and referenced in the current cleaning procedure, consists of the (b) (4) preparation of a solution containing BruClean™ detergent and applying this solution to all surfaces and floors within the cleanroom, including the ISO 5 laminar airflow workbenches, ISO 7 buffer areas, and ISO 8 anteroom areas; followed by a water rinse, and disinfection using isopropyl alcohol. The referenced rinsing and disinfectant agents are nonsterile. In addition, the use of BruClean as a nonsterile detergent is a repeat observation. There are no cleaning validation data supporting the removal of residues of this detergent.

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4. Section 8.3 of the current cleaning and maintenance procedure states that a "Texcide® soak is recommended (b) (4) in rooms where 70% IPA is used". However, there are currently no sporicidal agents used within the facility.
5. Efficacy studies have not been conducted to validate disinfectants, sanitizers, or sporicidal agents to determine minimum concentration, and contact time to achieve appropriate levels of disinfection for product and process-related contact surfaces.
6. Nonsterile (b) (4) cleaning wipes, (b) (4), are moistened with nonsterile isopropyl alcohol applied to surfaces within the ISO 5 laminar airflow workbench where aseptic processing of sterile products occur.
7. The daily, weekly and monthly cleaning activities are not periodically verified and documented to ensure the cleaning is performed and is effective, as stated in the current cleaning and maintenance procedures. Additionally, cleaning activities performed in the cleanroom have not been documented for a period covering January 1, 2018 through April 13, 2018.
8. ~~The above referenced procedure also states in section 9.5 that "cleaning shall be performed using a detergent followed by sanitization if there is any visible particulate". The cleaning regime within the ISO7 buffer room, ISO5 laminar flow workbenches and the ISO8 ante room, as stated by the sterile technician (b) (6) consists of the (b) (4) preparation and use of a solution of Bru-Clean™ detergent to~~

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~~clean all surfaces, followed by a water rinse and disinfection with Isopropyl alcohol. These cleaning and disinfecting agents are nonsterile. There is no cleaning validation data demonstrating the removal of detergent residue from aseptic processing area. The use of Bru Clean as a cleaning agent is a repeat observation.~~

~~9. Section 8.3 of the current cleaning procedure states that a "Texeide (sporicidal agent) soak is recommended (b) (4) in rooms where 70% IPA is used." However, no sporicidal agent is being used within the ISO8 ante room, ISO7 buffer room or the ISO5 laminar workflow benches.~~

~~10. Plastic dispensing bottles labeled to contain "Sterile IPA" were observed being used within the ISO7 buffer room and ISO8 ante room to sanitize equipment, process related materials, surfaces within the ISO5 laminar airflow work bench and as a hand sanitizer. However, the primary bulk container of Isopropyl Alcohol within the cleanroom was observed nonsterile. In addition, the dispensers are not cleaned and sanitized between uses.~~

OBSERVATION 3

Air is recirculated to production areas, without adequate measures to control recirculation of dust.

Specifically,

Air visualization pattern testing performed during (b) (4) recertification of the ISO 5 laminar airflow hoods located within the ISO 7 buffer room (i.e. smoke studies) is not documented (i.e. video or

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other means) to ensure unidirectional airflow is achieved without reflux, or from air turbulences from external or structural sources, and to ensure room air is recirculated properly through ceiling return air vents.

OBSERVATION 4

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its cleaning and maintenance.

Specifically,

The Nuaire ISO 5 laminar airflow workbench (model 301-630) is constructed with a non-stainless steel work surface which is bordered with a non-porous, particle board. This material is not easily cleanable and a potential source of particulate generation within the ISO 5 environment and ISO 7 buffer room, and a potential source of contamination of aseptically produced sterile drug product. The material also appears to be adhered to the work surface with tape. During the inspection, the workbench was used to prepare sterile FTM and TSB media plates used in the sterility testing of finished product. The use of this workbench in its present condition is a repeat observation.


OBSERVATION 5

An observation concerning (No cleaning records maintained from January 1, 2018 through April 13, 2018. Daily, weekly and monthly cleaning activities within the clean room to be documented and the effectiveness of the cleaning is to be periodically checked by environmental surveys.) was removed based on discussion with management.

OBSERVATION 6

Written records are not always made of investigations into unexplained discrepancies.

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Specifically,

- Per SOP 3.020, "Cleaning and Maintenance of the Clean Room Facility, ver.1.0, eff.2/15/2013, the temperature range within the buffer room and ante room shall be maintained at (b) (4) °C ((b) (4) °F) or colder. The humidity should be maintained in the range of (b) (4) - (b) (4) %. (b) (4) temperature and humidity monitoring records documented humidity excursions on the following days:

DATE	ANTE ROOM	BUFFER ROOM
1/12/2017	68%	
11/1/2017	68%	
11/2/2017	70%	
11/6/2017	67%	74%
11/7/2017		69%
11/10/2017	71%	
11/15/2017	70%	
11/16/2017	71%	
11/28/2017	68%	
11/30/2017	68%	
3/1/2018	67%	
3/5/2018	70%	
3/16/2018	70%	
3/19/2018	66%	
3/26/2018	72%	
3/27/2018	68%	
3/28/2018	69%	

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3/29/2018	70%	
4/3/2018	72%	

There was no investigation to determine the duration of these excursions or the impact to aseptic processing activities. Room conditions are documented only (b) (4).

2. Temperature and humidity monitoring records document that an air conditioning malfunction occurred on 11/6/2017 and compounding operations were suspended. There was no investigation of root cause, or a requalification of the cleanroom to assess potential impact to processing areas prior to resuming operations on 11/7/2017.

OBSERVATION 7


The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically,

Quality reviews are not consistently performed to ensure written procedures are revised to reflect all current policies and operational activities.

Records required to be maintained to ensure cleaning processes are followed and are appropriate; that processing equipment and instruments are calibrated, and all processing data generated during the production of drug products to ensure that the identity, strength, safety, and efficacy of such products are not negatively impacted, are not being reviewed and documented.

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OBSERVATION 8

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include validation of the sterilization process.

Specifically,

1. The current procedure, SOP 9.110, "Sterile Compounding process validation- Media Fill, ver. 3.0, eff. 11/21/2014, establishes the requirements for conducting "(b) (4)" media fills that result in a total of (b) (4) ml vials produced. The process for "(b) (4)" products, as defined within this SOP results in the preparation of a total of (b) (4) syringes produced. Neither of these media fills simulates actual production conditions or cover worst case or most challenging conditions. Typically, drug products are prepared in vials, syringes, and (b) (4) devices of varying sizes and batch sizes of up to (b) (4) units have been produced. For example,

- Lidocaine/Sodium Bicarbonate 0.5ml, lot 58867:42, produced on 4/2/2018, consisted of (b) (4) /3cc syringes

The inadequacy of your media fill process design is a **repeat observation**.

2. The aforementioned procedure requires all personnel responsible for aseptic processing of sterile preparations to complete "(b) (4) -media fills (b) (4)". However, the sterile technician's last media fill participation occurred on 9/28/2017.

3. Autoclave and dry heat oven cycles used to sterilize drug preparations and glassware are not validated. Cycle parameters for the autoclave are (b) (4) and dry heat oven cycle parameters are set via a (b) (4). Actual cycle parameters are not being recorded onto sterilization logs or formula worksheets

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4. Written procedures for bubble point testing have not been established. (b) (4) filters are used to filter sterilize drug products prepared from non-sterile drug substances. In observing the actual performance of this test, the sterile technician appeared to not fully pressurize the filter to ensure accurate results.

5. On 4/5/2018, during the aseptic processing of Hyaluronidase solution, lot 58895:42, sterile operator (b) (6) was observed retrieving a pressure gauge from a material storage shelving unit within the ISO 7 buffer room then return to the ISO 5 laminar airflow workbench and perform a bubble point filter integrity test without first disinfecting the gauge.

OBSERVATION 9

Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.

Specifically,

1. Your firm has not conducted bacterial endotoxin tests for sterile preparations that are aseptically filled, terminally sterilized by autoclave and terminally sterilized by dry heat oven since 10/1/2017. These products are prepared from non-sterile active pharmaceutical ingredients. Furthermore, the last documented evidence of a bacterial endotoxin test conducted by the firm was on February 20, 2017.

2. While your firm conducts sterility testing on your finished aseptically filled preparations, your firm does not conduct sterility testing on finished preparations that are terminally sterilized in the autoclave and/or dry heat oven. The terminal sterilization cycle for both the autoclave and dry heat oven has not been validated. **This is a repeat observation.**

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3. Your firm's sterile technician stated that sterility testing is (b) (4) aseptically filled preparations however, the sterility test method utilized at the firm is not an official method even though the formula worksheet refer to USP71 as the sterility method used. The firm's sterility test consists of (b) (4) (b) (4) which are incubated and read for (b) (4) days. There are no written procedures to describe the sterility test being used at the firm for all aseptically filled compounded preparations.

4. Your firm prepares Tryptic Soy Broth (TSB) agar and Fluid Thioglycollate Medium (FTM) agar which is used for conducting the firm's environmental testing, conducting media fills and sterility testing of aseptically filled preparations. Your firm does not use standard reference organisms such as ATCC cultures to conduct growth promotion to ensure that your media prepared in house can promote growth of gram negative and/or gram positive bacteria as well as yeast and molds. Currently, your aseptic technician's test for growth promotion is (b) (4), (b) (6) (b) (4), (b) (6) which is plated on the agar plates and placed in the incubator along with pending sterility samples.


5. Your firm sent Baclofen Inj 2mg/ml Lot #58096:42 to Pharmetric Laboratory for Sterility and Endotoxin testing. However, the sterility comments on the final report states that based on batch and sample size tested, it is not USP71 compliant.

OBSERVATION 10

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications and identity and strength of each active ingredient prior to release.

Specifically,

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<p>A) Your firm does not conduct potency testing on your sterile and non-sterile finished preparations to ensure that the active ingredients used in the finished compounded preparations have the identity and strength it is represented to possess. For example, no potency testing was conducted on the following preparations:</p> <ol style="list-style-type: none"> 1. Mitomycin 0.2mg/ml Lot #57134:42, BUD: 11/6/2017:14 days. 2. B-Complex 100ml Bag, Lot #57747:00, BUD: 12/13/2017: 90 days. 3. Ascorbic Acid 500mg/ml, Lot#58555:42, BUD: 5/28/2018: 84 days. 4. Sildenafil 200mg troche, Lot #58240:16. BUD: 03/31/2018: 180 days. 5. Benzocaine 20%, Lidocaine 8%, Tetracaine 6% (BLT) Topical Cream Lot #58268:97, BUD: 06/21/2018: 180 days. 6. Jessner's Solution Lot #58237:44, BUD:08/01/2018: 180 days. <p>B) Your firm does not test your non-sterile products for microbial enumeration nor do you test for specified microorganisms. Furthermore, acceptable levels of microorganisms within each non-sterile drug product have not been established:</p> <ol style="list-style-type: none"> 1. Sildenafil 200mg troche, Lot #58240:16, BUD: 03/31/2018: 180 days. 2. Benzocaine 20%, Lidocaine 8%, Tetracaine 6% (BLT) Topical Cream Lot #58268:97, BUD: 06/21/2018: 180 days. 3. Jessner's Solution Lot #58237:44, BUD: 06/21/2018: 180 days. <p>C) Your firm did not conduct any antimicrobial effectiveness tests for the drug preparations containing preservatives to ensure that the products retain antimicrobial effectiveness up to the beyond use dates given on the following drug preparations:</p>			
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SEE REVERSE OF THIS PAGE		<div style="display: flex; justify-content: space-between;"> <div style="width: 60%;"> <p>EMPLOYEE(S) SIGNATURE</p> <p>Patty P Kaewussdangkul, Investigator</p> <p>Lori G Cantin, FDA Center Employee or Employee of Other Federal Agencies</p> <p>Bonita S Chester, Investigator</p> </div> <div style="width: 35%; text-align: center;"> <p>X</p> <p><small>Patty P Kaewussdangkul Investigator Signed By Patty P. Kaewussdangkul -S Date Signed 04-23-2018 13:48:18</small></p> </div> </div>	
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1. B-Complex 100ml Bag, Lot #57747:00 with a BUD of 90 days.
2. Ascorbic Acid 500mg/ml, Lot #58555:42 with a BUD of 84 days.

OBSERVATION 11

Written procedures are not followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically,


A) Your firm routinely cleans stir bars, glass beakers and glass graduated cylinders with a non-pharmaceutical grade household dishwashing detergent ((b) (4) brand) before sterilization and/or depyrogenation. Your firm has not validated this cleaning process to ensure that it is adequate to prevent cross contamination of drug substances. Furthermore, your firm has not verified that leftover residues of the dishwashing detergent are absent in your preparations.

B) Your sterile technician stated that equipment used to make preparations is placed in the dishwasher with a non-pharmaceutical dishwashing detergent on a wash and dry cycle then ((b) (4)) prior to sterilization/depyrogenation. The firm's written procedure entitled, "((b) (4)) Sterilization (Depyrogenation)" SOP 8.040 states that compounding equipment is rinsed with sterile((b) (4))and allowed to dry prior to ((b) (4)) ((b) (4)) However, the sterile technician stated that he does not rinse equipment with sterile((b) (4))and that the written procedures are not being followed. Furthermore, no hold time studies have been conducted on the ((b) (4)) to ensure that equipment maintains sterility and/or depyrogenation for a specified amount of time.

OBSERVATION 12

There is a failure to thoroughly review 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.

AMENDMENT 1

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

DISTRICT ADDRESS AND PHONE NUMBER 4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax: (214)253-5314		DATE(S) OF INSPECTION 4/2/2018-4/20/2018*
		FBI NUMBER 3012669715
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Jack R. Munn, Owner		
FIRM NAME Guardian Pharmacy Services	STREET ADDRESS 7920 Elmbrook Dr Ste 108	
CITY, STATE, ZIP CODE, COUNTRY Dallas, TX 75247-4933	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drug Products	


Specifically,

Your firm failed to properly investigate the following failures:

1. Your firm initiated a sterility test on 9/22/2017 for Isoproterenol HCL 4mcg/ml Injection, Lot #56771:14 with a BUD of 12/21/2017. On 9/26/2017, Day 4 of the sterility test, growth was observed on the agar plates. Your firm's sterility test has not been validated. A recall was conducted however, the recall effectiveness could not be determined since the provided records did not state what was returned, how many was returned and who was responsible to ensure that the items returned was received. Furthermore, the investigation involved sending one vial growth to be tested by (b) (4) (b) (4) which came back sterile. The growth found on the plate was not sent for microbial identification.
2. On 2/13/2017, your firm conducted a bacterial endotoxin test on Ropivacaine 2mg/ml, Lot #53550:42. The test suitability failed and spike recovery failed. No investigation was conducted on this endotoxin test failure. This product was not recalled and distributed to your customer.
3. On 3/10/2017, your firm received a consumer complaint regarding Glycopyrrolate 0.2mg/ml, Lot #53766:14 not working. The firm's investigation consisted of reviewing the formula worksheet of the batch, review of the COA of the active pharmaceutical ingredient and sent a sample to (b) (4) for testing which confirmed the consumer's complaint. The potency of the product was tested at 32.9%. No root cause of the failure was determined and no recall was initiated.
4. Mitomycin 1ml syringe 0.4mg/ml, Lot # 55337:00 was sent out for beyond use testing to Eagle Analytical Services. The initial test failed potency at 81.5%. No investigation was conducted for this failure and the product was distributed to your customer. Furthermore, a recall was not conducted.

OBSERVATION 13

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There is no written testing program designed to assess the stability characteristics of drug products.

Specifically,

Your firm does not have a written stability program for establishing beyond use dates (BUD) that are placed on your compounded drug preparations. For example, the following BUD was given to:

1. Mitomycin 0.2mg/ml Lot #57134:42 is given a BUD of 14 days.
2. B-Complex 100ml Bag, Lot #57747:00 is given a BUD of 90 days.
3. Ascorbic Acid 500mg/ml, Lot#58555:42 is given a BUD of 84 days.
4. Sildenafil 200mg troche, Lot #58240:16 is given a BUD of 180 days.
5. Benzocaine 20%, Lidocaine 8%, Tetracaine 6% (BLT) Topical Cream
Lot #58268:97 is given a BUD of 180 days.
6. Jessner's Solution Lot #58237:44 is given a BUD of 180 days.

There is no data to support the beyond use dates given to these compounded preparations.


OBSERVATION 14

Procedures describing the handling of all written and oral complaints regarding a drug product are not followed.

Specifically,

Your firm's SOP entitled, "Complaints/Grievances and Adverse Reactions" SOP 5.030 Version 2.0 Effective 5/1/2013 states that all complaints received shall be initiated and resolved as quickly as possible. It also states that final conclusions shall occur within ^{(b) (4)} business days of receipt of complaint and Customer Complaint/Adverse Reaction Records are to be reviewed by the PIC or designee. In

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

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2017, there were a total of 23 complaints received that were not reviewed by the PIC or designee. **This is a repeat observation.**

OBSERVATION 15

Records of the calibration checks of automatic, mechanical or electronic equipment, including computers or related systems are not maintained.

Specifically,

Calibration records are not maintained for the following equipment used in aseptic processing activities:

1. Magnehelic pressure gauges used to ensure appropriate pressure differentials between the ISO 7 buffer room and ISO 8 ante room
2. Minihelic pressure gauges of the ISO 5 laminar airflow workbenches
3. Temperature and humidity probes within the incubators used for media plates and finished product sterility samples
4. (b) (4) used to obtain (b) (4) measurements (b) (4) of sterile preparations.

***DATES OF INSPECTION**

4/02/2018(Mon), 4/03/2018(Tue), 4/04/2018(Wed), 4/05/2018(Thu), 4/06/2018(Fri), 4/09/2018(Mon), 4/10/2018(Tue), 4/11/2018(Wed), 4/12/2018(Thu), 4/13/2018(Fri), 4/16/2018(Mon), 4/17/2018(Tue), 4/18/2018(Wed), 4/19/2018(Thu), 4/20/2018(Fri)

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