

**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 9/12/2016-10/21/2016*
	FEI 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

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

Specifically,

A. Media fills performed by your firm with each of the operators who work in the ISO5 area do not closely simulate actual production conditions or cover worst case or most challenging conditions. The media fill your firm performs has the operator filling 5 ml of media in three (3) test syringes and three (3) test vials. In routine production, your firm fills various size vials (2ml – 10ml) as well as syringes and batch sizes up to 300 units.

For example, on 8/22/16, your firm produced and dispensed 400- 3cc syringes containing 1ml of Hyaluronase 150U/ml Injectable preservative free (Lot# 50449:00) with a Beyond Use Date (BUD) of 11/10/2016.

B. Your firm has not validated the sterilization process for any of the drug products that you prepare.

For example,

- Your firm prepares Triamcinolone acetonide injectable and Medroxyprogesterone acetate suspension injectable and both are terminally sterilized using your autoclaves.
- Your firm prepares Nandrolone deconate injectable, Estradiol valerate Injectable and Testosterone

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cypionate Injectable, which are all terminally sterilized using your dry heat oven.

Additionally,

You do not consistently document the dry heat oven log for drug products which have been sterilized using the dry heat oven. The following drug products were not documented on the dry heat oven log:

- (i) Nandrolone Deconate in Oil 200mg/ml Injectable in 10 ml vials, Lot 49752:42, made on 7/11/16
- (ii) Nandrolone Deconate in Oil 200mg/ml Injectable in 10 ml vials, Lot 49141:00, made on 6/16/16
- (iii) Testosterone Cypionate in Sesame Oil 200mg/ml Injectable in 10 ml vial, Lot 50379:00, made on 8/16/16

C. Written procedures for bubble point testing have not been established. Your firm uses 0.22 micron filters to filter sterilize drug products prepared from non-sterile drug substances in the ISO 5 laminar flow hood. Your firm conducts bubble point testing using a bubble point gauge.

On 9/23/16 I observed a sterility failure on Day 14 of Lidocaine/Sodium Bicarbonate Injectable (Lot# 50699:00), batch size of 505 syringes (0.5ml in 3ml syringes). This was a drug product prepared from sterile drug substances, filter sterilized and dispensed for office use.

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OBSERVATION 2

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

Specifically,

Your firm does not conduct finished product testing for sterility on any of your terminally sterilized drug products. All of your terminally sterilized drug products are prepared from non-sterile bulk drug substances. Your firm has prepared and dispensed 15 lots terminally sterilized injectable drug products from 6/1/2016 to 9/9/2016.

OBSERVATION 3

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

Specifically,

D. Non-sterile disinfectants are routinely used by your employees during cleaning of aseptic processing areas, including the critical ISO 5 work area and ISO 7 areas including the clean room and ante room. Also, your firm does not utilize a sporicidal agent in the ISO 5 area. On 9/13/16, I observed the firm technicians disinfect the ISO 5 laminar flow hoods and ISO 7 clean room and ante room. The disinfectant used was non sterile disinfectant TexWipe TexQ, a quarternary ammonium disinfectant. The firm utilizes sterile 70% isopropyl alcohol as well as the following non sterile disinfectants on a rotational basis:

1. TexWipe TexQ Disinfectant (Quarternary Ammonium Disinfectant) (non-sterile)
2. TewWipe BruClean TbC Disinfectant Cleaner (Alternative to Bleach) (non-sterile)
3. Hydrogen peroxide 3% USP (non-sterile)

Additionally, your firm has failed to utilize a sporicidal agent in your rotational schedule of disinfectants.

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E. Your firm uses non-sterile wipes (CleanPro polycellulose, low particle, highly absorbent wipes) when disinfecting the ISO 5 laminar flow hood and the ISO 5 chemical hood where drug products are prepared.

OBSERVATION 4

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

Specifically,

Your environmental and personnel monitoring program is deficient in that your firm does not conduct air or surface sampling for viable or non-viable, particles during the aseptic operation of every batch or at least once per production day in which drug product(s), intended to be sterile are aseptically processed in your ISO 5 hood. Personnel monitoring of the operator's gloves has not been performed post aseptic processing of every batch or prior to exiting the Clean room. According to your Standard Operating Procedures (SOP), entitled Environmental Monitoring of the Clean Room Facility, Version 1.0, dated 04/12/16 and Pharmacist-In-Charge (PIC):

1. Personnel touch plates are conducted every two (2) weeks upon completion of sterile compounding and prior to cleaning
2. Surface sampling in the ISO 5 area are performed every two (2) weeks upon completion of sterile compounding and prior to cleaning
3. Viable and non viable air sampling are performed every 3 months during the clean room certification by third party vendor

During the previous six (6) month review of your environmental monitoring program, the personnel touch plate was performed on the following dates:

April	May	June	July	August	September
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2016	2016	2016	2016	2016	2016
4/1	513	6/24	7/4	8/8	9/2
4/29	5/27		7/19		9/16
					9/29

Additionally, the firm has not conducted monitoring every two weeks according to their SOP and there is no documented investigation, testing, document review or root cause identified for this deficiency.

From 6/1/16 through 9/12/16 you have prepared approximately 478 sterile drug products from non-sterile bulk and have prepared sterile drug products approximately 74 total days.

OBSERVATION 5

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically,

- A. On 05/27/16, a surface sample collected from the top shelf of the Glove cart located in the ISO 7 clean room had 9 colony forming units (CFUs). The firm's action limit for ISO 7 is 5 CFUs/plate.
- B. On 5/16/16, a surface sample collected at the sink located in the ISO 8 ante room had over 100 CFUs. The firm's action limit for ISO 8 is 20 CFUs/plate.

Additionally, the firm's SOP 3.030, Environmental Monitoring of the Clean Room Facility, version 1.0 states in section 9.10.3: "If an excursion occurs above an action level, the Pharmacist-In-Charge or Quality Control Officer must be notified and an investigation and correction action should occur." No investigation or corrective actions were documented for these excursions.

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C. Your firm does not consistently document that bubble point testing has been conducted on drug products. Your firm produced and dispensed the following drug products and failed to document on your Quality Control Data Sheet, that bubble point testing was conducted.

1. Hyaluronidase 150U/ml Injectable Preservative Free in 3cc syringes, Lot 50449:00, made on 8/19/16
2. Mitomycin 40mg/60ml solution Injectable in a 60ml syringe, Lot 50592:00, made on 8/30/16
3. Morphine 1mg/ml Injectable, Lot 49488:14, made on 6/23/16

There was no documented investigation or corrective actions were documented for these excursions.

D. On 05/03/16, Doxycycline 200mg stock solution (Lot 48541) was prepared and did not pass the endotoxin testing. No documented investigation or corrective actions were documented for this excursion. Furthermore, your SOP 8.010, Sterilization and Depyrogenation, version 1.0 fails to address necessary steps to take in case of an endotoxin failure.

OBSERVATION 6

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,

Your Nuair laminar flow hood, (Model 301-630, Serial Number 4246) has a stainless steel table supported by particle board which is difficult to clean and disinfect.

OBSERVATION 7

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The building lacks adequate space for the orderly placement of equipment and materials to prevent mix-ups between drug products and to prevent contamination.

Specifically,

Your firm prepares a hazardous cytotoxic drug product, Mitomycin in 1ml syringes, in the positive pressure ISO 7 clean room along with other non-hazardous products. Your firm has prepared and dispensed 16 lots (25 units or less for each lot) of this drug product since June 2016.

OBSERVATION 8

Procedures describing the handling of written and oral complaints related to drug products are deficiently written or followed.

Specifically,

Your complaint investigations are not followed as described in your SOP Number 5.030, Complaint/Grievances and Adverse Reactions, version 2.0, effective date: 05/01/2013, under section 9.7, which states "The PIC, or designee, should identify and document the specific facts involving the complaint." Your firm's PIC stated the firm has not documented complaints in the complaint log. Additionally, the firm's sterile supervisor stated the firm has received approximately six (6) customer complaints involving the elastomeric eclipse pump between January 2016 and May 2016. There is no documented investigation, testing, document review or root cause identified for this deficiency.

Furthermore, your complaint procedures do not include directions for defining an adverse event and the actions that the firm needs to take regarding the following complaints filed with Halyard Health, the manufacturer of the elastomeric pump utilized by your firm.

Date of Complaint	Product Description	Model	Lot/Serial #	Drug Product Prepared	Defect Description
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05/04/16	Eclipse 250/250	E252500	0202260864	0.9%Saline/ azithromycin 2mg/ml	Pump begin leaking as soon as the firm started to fill
05/12/16	On-Q 400ml	CB004	0202357033	0.9% Saline/ Ropivacaine 0.3%	Delivered to surgery center, all fluid leaked out before use
05/16/16	Eclipse 50/50	E050500	020234500	0.9% saline/ ceftriaxone 40mg/ml	Tubing was broken when removed from freezer
05/16/16	Eclipse 50/50	E050500	020234500	0.9% saline/ ceftriaxone 40mg/ml	Tubing was broken when removed from freezer
05/16/16	Eclipse 50/50	E050500	020234500	0.9% saline/ ceftriaxone 40mg/ml	Tubing was broken when removed from freezer
05/16/16	Eclipse 50/50	E050500	020234500	0.9% saline/ ceftriaxone 40mg/ml	Tubing was broken when removed from freezer

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In addition to not defining adverse events, you are not reporting them to the Food and Drug Administration and your firm failed to report these defective product issues.

Furthermore, an adverse event was reported by the consumer to the FDA on 05/27/16, regarding drug product, Ceftriaxone 2 gram in 50ml of 0.9% NaCl (Lot # 48058:42), prepared by your firm in an eclipse pump 50/50. This adverse event was known by your firm.

***DATES OF INSPECTION**

9/12/2016(Mon),9/13/2016(Tue),9/14/2016(Wed),9/15/2016(Thu),9/16/2016(Fri),9/19/2016(Mon),9/21/2016(Wed),9/23/2016(Fri),9/28/2016(Wed),10/03/2016(Mon),10/07/2016(Fri),10/11/2016(Tue),10/12/2016(Wed),10/21/2016(Fri)

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