DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax:(214) 253-5314 Industry Information: www.fda.gov/oc/industry	03/04/2013 - 03/08/2013* FEI NUMBER 3003431252

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Lowell J. Ahl, President

FIRM NAME	STREET ADDRESS
Lowlyn Pharmacies, Inc.	301 NE 10th St.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Blanchard, OK 73010	Producer of 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 are not established.

Specifically,

a) Your firm does not have any written procedures describing how aseptic operations are to be performed in the ISO 5 and ISO 7 classified areas. On 3/4/13 employee (b) was observed performing a sterile (b)(4) of Pyrilamine Maleate 25mg/mL injectable (lot #CABDADAE:37) with both sleeves of her gown rolled up to her elbows, exposing bare skin from the wrist to the elbow. The employee was observed walking directly into the clean room area without proper gowning, placing the beaker of drug product under the ISO 5 hood, returning to the ISO 8 Ante Room to gown up and then returned to the ISO 7 Clean Room/ISO 5 Laminar Flow Hood to continue sterilization and filling of the drug product. A similar process was observed, with the exception of the rolled up sleeves, on 3/5/13 during the preparation of Ketamine 200mg/mL injectable lot #CABDADAF:13 by employee (b) .

b) On 3/5/13, during the preparation of Amikacin (745) Buffered 50mg/mL injectable, lot #CABDADAF:25, the product was (b)(4) through a (b) (4) in an unclassified area and then placed into a vial, stoppered and (b) (4) sterilized. You stated that for some sterile animal products that are (b) (4) sterilized, your preparation instructions allow for the product to be (b) (4) for removal of particulates and then (b) (4) sterilized. You use a (b) (4) to perform this (b) (b)(4) .

c) Your firm does not perform (b) integrity testing of the (b) (4) sterilizing (b)(4) used to prepare sterile drug products. This applies to all sterile drug products, human and animal preparations that are (b)(4) sterilized.

OBSERVATION 2

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

Specifically,

a) Your firm has not performed any media fills.

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	Margaret M. Annes, CSO Margaret M. Annes, CSO Torrance J. Slayton, CSO Torrance J. Slayton, CSO	03/08/2013

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b) There is no assurance that your firm has adequate process controls to prevent failures of your sterile drug product. For example, the sterilization processes for suspensions and solutions have not been designed following a scientific rationale. Suspensions are (b) (4) , and solutions are (b) sterilized with a (b) (4) sterile (b) . There is no data to support the (b) (4) cycle of (b) (4) that is applied to all suspensions and no data to support that the (b) (4) sterilizing (b) (4)) are suitable to ensure sterile products.

OBSERVATION 3

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

Specifically, your firm does not have a written environmental monitoring plan. No environmental monitoring, including personnel monitoring, is performed under static or dynamic conditions.

OBSERVATION 4

Employees engaged in the processing of a drug product lack the training required to perform their assigned functions.

Specifically , your firm does not have documentation to show that all employees involved in the preparation of sterile drug products have been trained. Employee (b) has no documented training for the preparation of sterile drug products. Employee (b) attended a (b) (4) "Aseptic Compounding Training" course in July 2005 but has no other documented training related to aseptic processing of drug products. During this inspection on 3/4/13 & 3/5/13, we observed Employee (b) preparing sterile drug products (lot #CABDADAE:37 of Pyrilamine Maleate USP 25mg/mL injectable, lot #CABDADAF:25 of Amikacin (745) Buffered 50mg/mL injectable, and lot #CABDADAF:13 of Ketamine 200mg/mL injectable) without properly gowning, including preparing sterile drug products in an ISO 5 laminar flow hood with the sleeves of her gown rolled up to the elbow exposing bare arms.

OBSERVATION 5

Clothing of personnel engaged in the processing of drug products is not appropriate for the duties they perform.

Specifically, your firm has no written procedures for gowning to enter the ISO 5/ISO 7/ISO 8 classified areas. The general gowning for entry into the ISO 5/ISO 7 classified areas consists of the following that are not sterile and not lint free: a single pair of shoe covers, a single lab coat, a single hair net and a single ear-loop face mask. The operator also used a single pair of sterile gloves which are donned inside the ISO 5 laminar flow hood. On 3/4/13, employee (b) was observed preparing ((b) sterilizing into an open vial and then stoppering the vial) Pyrilamine Maleate USP 25mg/mL injectable on 3/4/13 (lot #CABDADAE:37), was observed not wearing shoe covers and had the sleeves of her gown rolled up to her elbows, exposing bare skin from the wrist to the elbow while under the ISO 5 laminar flow hood. The general gowning requirements leave exposed skin around the eyes, forehead and neck of the person preparing the sterile drug product.

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OBSERVATION 6

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

Specifically, your firm's cleaning and disinfection of the ISO-8 Ante Room, ISO-7 Clean Room (b) Room), and ISO-5 laminar flow hood does not ensure aseptic conditions. For example,

a) Your firm uses non-sterile (b) (4) treated with non-sterile (b) (4) to disinfect surfaces inside the ISO-5 laminar flow hood. There is no evidence that these (b) (4) are composed of non-shedding material and there has been no evaluation of the effectiveness of using (b) (4) to disinfect the work surfaces in the ISO-5 classified area. We observed the use of the above items prior to the aseptic filling of veterinary drug products ((lot #CABDADAE:37 of Pyrilamine Maleate USP 25mg/mL injectable, lot #CABDADAF:25 of Amikacin (745) Buffered 50mg/mL injectable, and lot #CABDADAF:13 of Ketamine 200mg/mL injectable) on 3/4/13 and 3/5/13.

b) Your firm employs no sporicidal agents in the disinfection of the ISO-8 area, ISO-7 area, or ISO-5 laminar flow hood.

c) The mop used to clean the floors in the ISO 8 and ISO 7 classified areas is a sponge and is not composed of non-shedding material.

d) Your firm has no written procedures for conducting cleaning of the ISO-8 Ante Room, ISO-7 Clean Room, and ISO 5 laminar flow hood.

OBSERVATION 7

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

Specifically, the design of your firm's ISO-8 Ante Room and ISO-7 Clean Room (b) Room), which contains your ISO-5 laminar flow hood, does not ensure sufficient quality of air necessary to prevent contamination of your sterile drug products. For example, there is no door or other barrier between the unclassified processing area (lab) and the ante room, and between the ante room and clean room, necessary to create an air pressure differential. The current ISO classification of your rooms is only supported by the (b) (4) qualification by a third-party according to the displacement airflow principle. There is no routine monitoring by any method to support the day-to-day status of these areas.

On 3/4/13 we observed the preparation of lot #CABDADAE:37 of Pyrilamine Maleate USP 25mg/mL injectable. On 3/5/13 we observed the preparation of lot #CABDADAF:25 of Amikacin (745) Buffered 50mg/mL injectable and lot #CABDADAF:13 of Ketamine 200mg/mL injectable.

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OBSERVATION 8

Drug product containers and closures were not clean and sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use.

Specifically, your firm's preparation of glass vials and rubber stoppers for use in sterile animal drug products does not ensure they are pyrogen free prior to use. For example,

a) Your firm receives glass vials and rubber stoppers that are not depyrogenated and will be filled with non-sterile drug product and then (b)(4) sterilized or aseptically filled.

b) The glass vial preparation includes washing in a household-type dishwasher with household detergent, enclosed in (b) (4) and then (b) (4)

c) The stoppers are prepared by removing them from the clear plastic shipping bag, wrapping them with (b) (4) (b) (4), and then (b) (4)

d) Your firm has no evidence that these glass vials and rubber stoppers were depyrogenated by your supplier. In addition, there are no written procedures or records of vial or stopper preparation.

OBSERVATION 9

Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.

Specifically, your firm does not conduct routine sterility or endotoxin testing for all sterile drug products currently produced. For example, you stated that some products are tested (b) (4) according to a (b) (4) schedule. On 3/8/13, we observed (XXX) different sterile injectable animal drug products that were approved for shipment to customers. None of these products had been tested for sterility or endotoxins prior to release. The products observed include:

- Acetyl-D-Glucosamine 20% 200mg/mL injectable (lot #CABDADAE:33)
- Diclazuril 500mg/mL injectable (lot #CABDACCB:22)
- Cyclosporine 2% Ophthalmic (lot #CABDADAE:34)

In addition, there is no established written program for conducting sterility and endotoxin testing.

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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, your firm does not conduct potency testing for all sterile drug products currently produced. For example, you stated that some products are tested (b) (4) according to a (b) (4) schedule. On 3/8/13, we observed (XXX) different sterile injectable animal drug products that were approved for shipment to customers. None of these products had been tested prior to release. The products observed include:

- Acetyl-D-Glucosamine 20% 200mg/mL injectable (lot #CABDADAE:33)
- Diclazuril 500mg/mL injectable (lot #CABDACCB:22)
- Cyclosporine 2% Ophthalmic (lot #CABDADAE:34)

In addition, there is no established written program for conducting potency testing.

OBSERVATION 11

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

Specifically,

a) Your firm does not have a written stability program to justify the Beyond Use Date (BUD) placed on sterile drug products. Your firm does not have any documentation to justify how the current BUD's were established for each sterile drug product.

For example, on the Papaverine/Phentolamine/Prostaglandin 30mg/1.5mcg/30mcg/mL product (human sterile drug) you place a BUD of 180 days. On the Budesonide 5mg/mL product (animal sterile drug) you place a BUD of 90 days.

b) Your firm failed to perform any anti-microbial effectiveness testing to determine whether ingredients such as (b) (4) (b) (4) effectively inhibit microbial growth in your sterile injectable drug products through their BUD period.

OBSERVATION 12

Equipment and utensils are not cleaned and sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically, your firm's cleaning and disinfection of processing utensils and containers does not ensure they do not contaminate your sterile injectable drug products. For example,

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a) Your firm cleans equipment and utensils, including glass beakers used to process drug products prior to sterilization, by hand-washing in a sink with (b) (4) household dish detergent and then in a household style dishwasher using (b) (4) (b) household dishwasher detergent. The water supplied to the sink and dishwasher are municipal source and is not further treated. Your firm has no evidence that this cleaning method is appropriate for equipment and utensils used to produce sterile drug products.

b) Your firm uses a pair of tweezers to conducted manipulations in the ISO 5 laminar flow hood of rubber stoppers used to seal glass vials containing animal drug products after (b) sterilization or (b) (4) sterilization. The tweezers are not (b) prior to use and are disinfected by placing the end of the tweezers in a beaker with non-sterile (b) (4).

c) Your firm (b) sterilizes bulk non-sterile drug products in (b) (4) from a beaker via an aseptic process in the ISO-5 laminar flow hood. The non-sterile drug product is mixed in the beaker located in an unclassified room and then moved to the laminar flow hood without conducting any disinfection of the beaker.

*** DATES OF INSPECTION:**
03/04/2013(Mon), 03/05/2013(Tue), 03/08/2013(Fri)

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