DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	4/9/2018-5/7/2018* FEI NUMBER 3004483463

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Hal J. Weaver, President

FIRM NAME	STREET ADDRESS
Coast Quality Pharmacy LLC	5710 Hoover Blvd
CITY, STATE, ZIP CODE, COUNTRY Tampa, FL 33634-5339	TYPE ESTABLISHMENT INSPECTED Preparer 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

You used a non-pharmaceutical grade component in the formulation of a drug product.

Specifically, the components In-111 (b) (4) and diethylenetriaminepentaacetic acid (DTPA) used to prepare radiopharmaceuticals such as In-111-DTPA for cisternography are a non-pharmaceutical grade and have not been tested for microorganisms or endotoxins by the manufacturer. You do not perform and have not performed the following testing on the In-111 (b) (4)

1.) Chemical impurities such as Cd which is the target material

2.) Radiochemical purity

3.) Radionuclide purity

4.) Microorganisms

5.) Yeasts and Mold

6.) Endotoxins

In addition on 4/12/2018, we also observed the following during the sterile drug preparations of In-111-DTPA lot In-DTPA180412RA for intrathecal use using (b) (4) (b) (4) lot (b) (4) and

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	Joanne E King, Investigator Jennifer L Huntington, Investigator Christie A Soto, Investigator	X Joanne E King Investigator Signed By 1300174867 Date Signed 05-07-2018 14 46 39	5/7/2018

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(b) (4) DTPA lot (b) (4) made using DTPA lot (b) (4) in the Dispensing (b) (4) clean room:

(b) (4) was removed from the stock vial containing (b) (4) (b) (4) using a hypodermic needle and syringe. The (b) (4) (b) (4) Some of this (b) (4) was then returned back into the stock bottle using the same needle and syringe when it was determined that the (b) (4) . This practice could increase the endotoxin load.

B. (b) (4) of in process In-111-DTPA was withdrawn with a syringe (b) (4) (b) (4) (b) (4) This was then returned to the in process bulk In111-DTPA (b) (4) vial. This practice could increase the endotoxin load.

C. The quality control sample for In-111-DTPA is not a representative sample in that it is a (b) (4) rinse of the syringe used to fill the finished drug preparation vials rather than a finished drug product preparation. This non representative sample is used by you to evaluate endotoxins which are not removed by (b) (4) or (b) (4) cycles.

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written and followed.

Specifically, we observed the following deficiencies:

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A. Procedures have not been established for performing and evaluating smoke studies under dynamic conditions. In addition, your firm lacks smoke studies demonstrating unidirectional laminar airflow during the most complex processes performed at your facility.

B. Environmental monitoring of the ISO 7 Dispensing (b) (4) buffer room and the Ante room ISO8 ((b) (4)) recovered in the past 3 months the following objectionable organisms and corrective actions and preventive actions were not documented to demonstrate appropriate measures to remove these objectionable organisms:

In Buffer Room ISO 7(b) (4):

1.) Coagulase-negative *Staphylococcus*

2.) Non-sporulating *Dematiaceous* fungus

3.) *Cladosporium spp.*

4.) *Bacillus spp.*

In Ante-Room ISO 8 (b) (4):

1.) *Bacillus spp.*

C. Trays with partially stoppered vials containing (b) (4) and (b) (4) (b) (4) (b) (4) particle count per vial (b) (4) for injection that are filled without the use of a (b) (4) are carried out of the ISO 5 classified laminar air flow hoods and across the buffer room (b) (4) which is classified as an ISO 7 area to your (b) (4) machines.

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D. You have not validated your (b) (4) machines that open up into your (b) (4) clean room. As a result we observed that your (b) (4) (b) (4) (b) (4) prepared on 4/6/2018 was stuck in the (b) (4) cycle in (b) (4) as of 4/12/2018.

E. We observed several trays of what were explained to us as commercially non-pyrogenic and sterile vials to be filled with sterile drug preparations for lyophilization. These vials were de-crimped and being stored on a shelf in the buffer room (b) (4) under ISO 7 conditions. Some of these vials had trays resting on their stoppers or were visibly on their sides and the amount of time they were stored de-crimped was not documented

OBSERVATION 3

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

Specifically,

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A. Surface and air monitoring of the ISO-5 classified laminar airflow workstations (LAFW) is not conducted at least daily, despite production of sterile drug products.

B. Personnel monitoring, including fingertip sampling, of operators involved in sterile operations of intrathecal drug products in the ISO-5 LAFW is not conducted at least daily.

(*This is a repeat from the previous inspection date 02/19-22/13*)

OBSERVATION 4

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

Specifically,

A. The suitability, efficacy, and limitations of disinfecting agents and procedures have not been assessed to ensure potential contaminants are adequately removed from surfaces in the ISO classified areas. (*This is a repeat from the previous inspection date 02/19-22/13*)

B. (b) (4) laminar flow hoods located in clean room (b) (4) had observable cracks in the plastic which is located directly over the ISO 5 areas where your filling operations are performed for (b) (4) without the use of (b) (4) .

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OBSERVATION 5

Written procedures are lacking which describe in sufficient detail the receipt, identification, storage, handling, sampling, testing, approval and rejection of components, drug product containers and closures.

Specifically, your firm accepts components (excipients), containers (glass vials, bags, syringes), and closures (rubber stoppers) without sampling and examination to ensure they are adequate for their intended use. In addition, your firm lacked written procedures and specifications for the control and acceptance of all containers and closures. (*This is a repeat from the previous inspection date 02/19-22/13*)

OBSERVATION 6

Investigations of an unexplained discrepancy and a failure of a batch or any of its components to meet any of its specifications did not extend to other batches of the same drug product.

Specifically, batches of (b) (4) were documented as discarded in your drug preparation documentation and reference to the investigation and extending this investigation to other batches was not documented. Examples of this include:

1. (b) (4) lot (b) (4) for radiochemical purity.
2. (b) (4) lot (b) (4) and (b) (4) for liver uptake.

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3. (b) (4) lot (b) (4) and (b) (4) for particle size.

OBSERVATION 7

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

Specifically, dispensing room (b) (4) which was qualified as an ISO 7 buffer room containing (b) (4) laminar flow hoods qualified as an ISO 5 where the sterile drug filling of vials for lyophilization containing (b) (4) for injection is preformed did not have air return vents and exit air flow was achieved through the area around the stainless steel swing door.

OBSERVATION 8

The written stability program for drug products does not include reliable, meaningful and specific test methods.

Specifically, your stability test results for lyophilized sterile drugs prepared by your firm does not include testing and results at meaningful time intervals for your established beyond use dates for the following:

1.) Chemical impurities

2.) Microorganisms

3.) Yeasts and Mold

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4.) Endotoxins

OBSERVATION 9

Equipment was and Materials or supplies were not disinfected prior to entering the aseptic processing areas.

Specifically, we observed the following poor aseptic techniques prior to sterile drug preparations in the ISO 5 work bench:

A. On 4/11/ 2018, we observed the following during the sterile drug preparations of Baclofen 4mg/mL Premix, lot (b) (4), and Morphine 50mg/mL Premix, lot (b) (4) both for intrathecal use:

1. We observed operators placing non-sterile wipes into the ISO 5 LAFW prior to the addition of sterile (b) (4). (*This is a repeat from the previous inspection date 02/19-22/13*)
2. Operators placed items including a scale, a heater, and a wrapped glass flask, into the ISO 5 LAFWs prior to sterilizing with sterile (b) (4).

B. On 4/12/2018, we observed the following during the sterile drug preparations of In-111-DTPA lot In-DTPA180412RA for intrathecal use using (b) (4) in (b) (4) lot (b) (4) in the Dispensing (b) (4) clean room:

1. The stopper on the (b) (4) in (b) (4) was wiped off using an (b) (4) pad with metal tongs that were hung on a hook in the biological safety cabinet (BSC) (b) (4) by the clean end rather than the handle. These tongs were also used to wipe the in process bulk In111-DTPA (b) (4) vial stopper prior to the insertion of a (b) (4) and (b) (4) (b) (4)

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2. The employee preparing the In-111-DTPA was observed touching the inside of a waste bag kept in the BSC (b) (4) with sterile gloves and returning to aseptic manipulations for adding (b) (4) to the in process In111-DTPA vial without spraying .

3. In the BSC (b) (4) vials of In-111-DTPA were drawn from the stock vial containing In111-DTPA using the same needle and syringe. No (b) (4) step during this process was performed. This syringe and needle were used to fill 5ml vials that were then re-stoppered and crimped using a hand held crimper in the ISO 5 area after filling each (b) (4) 5 ml vial.

OBSERVATION 10

Personnel moved rapidly in the vicinity of open sterile units and instruments, which disrupted the airflow and increased the risk of bringing lesser quality air into the ISO 5 classified aseptic processing area.

Specifically, we observed operators performing rapid movements while preparing intrathecal baclofen and morphine sterile drug preparations within the ISO 5 LAFWs on 04/09/18 and 04/11/18.

OBSERVATION 11

Personnel donned gowning apparel improperly, in a way that may have caused the gowning apparel to become contaminated.

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Specifically, we observed the following poor gowning techniques during the sterile drug preparations of Baclofen 4mg/mL Premix, lot (b) (4) and Morphine 50mg/mL Premix, lot (b) (4) both for intrathecal use:

1. Operators exhibited poor gowning techniques, which per the Quality Assurance Manager, were the procedures routinely used by the firm. Examples include, but are not limited to: hanging sterile gown on non-sterile rack prior to donning gown and touching sleeves with bare hands prior to donning sterile gloves.
2. Per your procedure P-404, Hand Hygiene and Garbing Procedure, operators are to don a (b) (4) or equivalent garment. All operators observed on wore a sterile gown, with non-sterile bouffant and shoe covers.
3. The operator who produced Morphine 50mg/mL Premix, Lot (b) (4) went behind the ISO 5 laminar airflow workstation (LAFW) to plug in the scale and touched the back of the ISO 5 hoods and the ISO 7 wall. The operator donned new sterile gloves however she did not re-gown prior to continuing operations in the ISO 5 hood.
4. Operators performing aseptic operations in ISO 5 hoods re-use sterile cloth gowns throughout a production day. As sampling of sleeves is not performed, your firm has no assurance that the sterility of the sleeves is maintained. (*This is a repeat from the previous inspection date 02/19-22/13*)

OBSERVATION 12

The ISO 5 classified aseptic processing areas and segregated production areas surrounding the ISO 5 classified aseptic processing area contained dust-collecting overhangs without adequate and frequent cleaning.

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Specifically,

A. We observed exposed, (b) (4) filters on the top of all (b) (4) ISO 5 LAFWs in Clean room (b)(4) which do not allow for complete sanitization of the ISO 5 LAFWs.

B.) Your bio safety cabinet (b)(4) located in your clean room (b)(4) where you prepare In-111-DTPA had visible peeling duck tape on the side of the cabinet that appeared to be covering two electric wire pass through holes that opened up directly to the ISO 5 work area where semi-aseptic drug preparations are performed.

OBSERVATION 13

You did not make adequate product evaluation and take remedial action where actionable microbial contamination was found to be present in the ISO 5 classified aseptic processing area during aseptic production.

Specifically, on 02/23/18, an out-of-specification (OOS) that recovered Coagulase-negative *Staphylococcus spp.* for routine Gloved Fingertip Sampling (GFS right 3 colonies and GFS left 16 colonies) performed on 02/20/18 was observed by your firm. The investigation performed is deficient for the following reasons: the investigation does not document if additional videos were reviewed and the results of those video reviews; the investigation does not address the potential contamination risks of

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the batch produced immediately prior to the positive GFS; and the investigation does not extend to additional batches produced on 02/20/18 by the employee.

***DATES OF INSPECTION**

4/09/2018(Mon), 4/10/2018(Tue), 4/11/2018(Wed), 4/12/2018(Thu), 4/13/2018(Fri), 5/07/2018(Mon)

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