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

| DISTRICT OFFICE ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| San Francisco District<br>1431 Harbor Bay Parkway<br>Alameda, CA 94502-7070<br>(510) 337 6801<br>Industry Information: www.fda.gov/oc/industry | 12/12-20/2016 |
| | FEI NUMBER<br>3011888866 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Sean M. Barclay, PharmD, Owner

| FIRM NAME | STREET ADDRESS |
|---|---|
| Barclay Luke & Pillai Specialty Pharmacy PLLC | 8352 W. Warm Springs Road, Suite 120 |
| CITY, STATE AND ZIP CODE | TYPE OF ESTABLISHMENT INSPECTED |
| Las Vegas, NV 89113 | 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 (I) (WE) OBSERVED:

OBSERVATION 1

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

Specifically,

Video recordings taken during sterile production as well as our observations during the inspection revealed inappropriate aseptic techniques used during production, including:

A. We observed your firm's sterile production of Meta PT Eye Drops Solution (Phenylephrine HCl 2.5%, Tropicamide 1% Ophthalmic Liquid Solution), Lot# 112716sb, which occurred on 11/27/2016. The sash of the (b) (4) Laminar Air Flow Hood (LAFH) was in an upright opened position the entire time. This can adversely affect the air intake. This can affect the air intake and HEPA unidirectional air flow of the critical ISO 5 zone.

B. On 12/14/2016, we observed the sterile production of Meta PT Eye Drops Solution (Phenylephrine HCl 2.5%, Tropicamide 1% Ophthalmic Liquid Solution) Lot# 121416jp. This is a (b) (4) product.

i. We observed Pharmacist (b) (7) (C), (b) (6) placing (b) (7) (C), (b) (6) arms and hands directly over sterile open vials, during filling operations, blocking the path of HEPA unidirectional airflow off the ISO 5 zone.

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ii. We observed a sterile lint free wipe placed over the front grille of the LAFH, obstructing the air intake of the ISO 5 LAFH.

iii. We observed the pharmacist spray (b) (6) gloves with sterile (b) (4), but did not allow the (b) (4) to dry before proceeding with further sterile drug production.

C. Your firm performed media fill using (b) (4) However, the (b) (4) procedure does not simulate your actual production process. For example, the current media fill procedure does not include (b) (4) Also, the largest batch prepared by your firm was (b) (4) while only (b) (4) were prepared following the (b) (4).

D. Your firm does not consistently perform and document the (b) (4) to ensure your (b) (4) are (b) (4) On 12/14/2016, we observed the (b) (4) of Meta PT Eye Drops Solution (Phenylephrine HCl 2.5%, Tropicamide 1% Ophthalmic Liquid Solution), Lot #121416jp. (b) (4) Pharmacist (b) (6) (b) (6), (b) (7)(C) (b) (4) therefore the test could not be performed. In addition, our review of your (b) (4) Log revealed you did not perform the (b) (4) during production of Meta PT Eye Drops Solution (Phenylephrine HCl 2.5%, Tropicamide 1% Ophthalmic Liquid Solution) , Lot #112716sb, on 11/27/2016.

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OBSERVATION 2

Buildings used in the manufacture, processing, packing, or holding of a drug product do not have the suitable construction to facilitate cleaning, maintenance, and proper operations.

Specifically,

A. Your firm's cleanroom design is inadequate in that there are two rows of grilles from the ISO 7 cleanroom directly into the unclassified area of the facility. We observed the openings, within each grille, were approximately 1/16 to 1/2 inch wide. The openings can be adjusted to as wide as approximately 1 inch. The dimensions of each grille are approximately 12 x 47 inches. If there is a loss of positive pressure from the ISO 7 cleanroom, there could be potential backflow of air from the unclassified area into the ISO 7 cleanroom.

B. On 12/14/2016, we observed Pharmacist (b) (6) perform (b) (4) cleaning of the ISO 7 cleanroom and ISO 5 LAFH. We observed (b) (6) did not follow the minimum (b) (4) dwell time required for sporicidal activity of the disinfectant. For example, he cleaned the inside of the ISO 5 LAFH sash with the sporicidal disinfectant and wiped the disinfectant after approximately (b) (4) .

C. Your firm's (b) (4) certification of your ISO 5 LAFH is not performed under dynamic conditions representing actual use during production. For example, on 12/14/2016, (b) (4) aseptic operations in the ISO 5 LAFH while producing Meta PT Eye Drops Solution (Phenylephrine HCL 2.5%, Tropicamide 1% Ophthalmic Liquid Solution). Your (b) (4) (b) (4) (b) (4) Furthermore, your firm does not maintain a video to document the air flow patterns observed during your (b) (4) certification.

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D. Your firm failed to perform environmental and personnel monitoring during the production of sterile drug products. Environmental monitoring performed on a (b) (4) was not performed under dynamic conditions simulating actual operations. For example, we observed (b) (4) producing Meta PT Eye Drops Solution (Phenylephrine HCL 2.5%, Tropicamide 1% Ophthalmic Liquid Solution) on 12/14/2016, but (b) (4) of your ISO 5 LAFH does not indicate it was performed under dynamic conditions, including (b) (4) Environmental and personnel monitoring was not performed during the production of this batch.

E. Your firm currently (b) (4) in the ISO 7 cleanroom, which according to Pharmacist (b) (7)(C), (b) (6), was last used on 12/09/2016. The (b) (4), which (b) (4), can (b) (4) (b) (4) in the ISO 7 cleanroom, (b) (4) and during (b) (4) The (b) (4) is used for (b) (4) purposes and for equipment including (b) (4) (b) (4)

OBSERVATION 3
Clothing of personnel engaged in the manufacturing and processing of drug products is not appropriate for the duties they perform.

Specifically,

Video recordings taken during sterile production as well as our observations during the inspection revealed inappropriate gowning was used during production, including:

A. We observed your pharmacists on multiple occasions enter the cleanroom area with inadequate gowning. For example, on 11/09/2016, 11/30/2016, and 12/05/2016, pharmacists entered the ISO 7 cleanroom wearing only street clothes (i.e. no cleanroom garb at all).

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Also, on 11/10/2016, 11/27/2016, and 12/05/2016, we observed the pharmacists donning non-sterile gowns open in the back, non-sterile gloves, and non-sterile head cover while performing sterile drug production.

B. On 11/27/2016 your firm produced Meta PT Eye Drops Solution (Phenylephrine HCl 2.5%, Tropicamide 1% Ophthalmic Liquid Solution) Lot# 112716sb. We observed non-sterile head covers, non-sterile gowns with open backs, and non-sterile foot covers were donned, non-sterile gloves were worn by Pharmacist (b) (6), (b) (7)(C) The only sterile garb worn by the pharmacists were sterile masks. Also, eye goggles were not used. We observed the pharmacists' eyes, skins on the forehead, both cheeks, and entire neck areas were exposed.

C. On 12/14/2016 your firm produced Meta PT Eye Drops Solution (Phenylephrine HCl 2.5%, Tropicamide 1% Ophthalmic Liquid Solution) Lot# 121416jp. Sterile apparel was donned; however, gowning was performed in such a manner as to compromise the sterility of the apparel. For example, we observed the pharmacist using bare hands to handle and don sterile mask, sterile googles, and sterile gowns. Additionally, we observed the sleeves and legs of the sterile gown were allowed to touch the dirty side of the anteroom floor. Also, when donning sterile gloves, we observed the pharmacist touched the sterile gloves surfaces with bare hands.

OBSERVATION 4

The quality control unit lacks authority to review production records to assure that no errors have occurred and fully investigate errors that have occurred.

Specifically, your firm has not established a quality control unit to verify production and control records are accurate and complete. Compounding records we reviewed revealed instances where Pharmacists are performing sterile production and also (b) (4).

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Also, on multiple occasions, your firm's pharmacists falsified records such as the Sterile Room Documentation Log for 2016.

A. Your firm's pressure gauges have not been calibrated since your cleanroom was installed in (b) (4) . In addition, there were no identifiers for the pressure gauges to determine which gauge is used to identify the pressure from each area of the facility. Furthermore on 12/12/2016, Pharmacist (b) (6), (b) (7)(C) signed the log book indicating the pressure gauges were within the specified range. However, when questioned, he was unable to identify which pressure gauge corresponded to each area of the facility. After your firm placed labels on the pressure gauges, we observed the pressure gauge for the (b) (4) read "0" in the morning and afternoon of 12/12/2016. The (b) (4) is required to maintain positive pressure at all times.

B. Your firm documents the (b) (4) disinfection/cleaning of the cleanroom and anteroom in the Sterile Room Documentation Log for 2016. We observed that the log was completed on multiple days when cleaning was either not performed or not completed according to your firms written procedures, as evidenced during our review of your video recordings including the following days:

i. On 11/27/2016, (b) (4) of Meta PT Eye Drops Solution (Phenylephrine HCl 2.5%, Tropicamide 1% Ophthalmic Liquid Solution) were produced.

ii. On 12/05/2016, (b) (4) of 0.2% Cyclosporine and (b) (4) of 1.0% Cyclosporine eye drops were produced.

OBSERVATION 5
Employees engaged in the manufacture and processing of a drug product lack the education, training and experience required to perform their assigned functions.

Specifically,

Your firm does not maintain a formal training program.

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Throughout the inspection and our review of your firm's video records, we observed multiple deficiencies regarding your firm's pharmacists' lack of training and experience as evidenced by inappropriate and inadequate gowning of pharmacists in the ISO 7 cleanroom, cleaning operations not being performed, inadequate aseptic technique of pharmacists in the ISO 5 LAFH, and failing to perform the (b) (4)

OBSERVATION 6

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

Specifically,

A. Your firm has not demonstrated product suitability according to the compendial method for the sterility testing of Meta PT Eye Drops Solution (Phenylephrine HCL 2.5%, Tropicamide 1% Ophthalmic Liquid Solution). Your firm has distributed this product to customers prior to demonstrating method suitability.

B. Your firm does not perform sterility, endotoxin, and potency testing on each lot of sterile patient specific drug produced, for example, HCG pre-filled syringes, and Caffeine benzoate liter bags.

OBSERVATION 7

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

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Specifically,

A. Each batch of your firm's sterile drug product; Meta PT Eye Drops Solution (Phenylephrine HCL 2.5%, Tropicamide 1% Ophthalmic Liquid Solution) is tested for potency by a contract testing laboratory. However, the potency testing method for Meta PT Eye Drops Solution (Phenylephrine HCL 2.5%, Tropicamide 1% Ophthalmic Liquid Solution) has not been validated to assure method suitability.

B. Your firm's sterile drug product Meta PT Eye Drops Solution (Phenylephrine HCL 2.5%, Tropicamide 1% Ophthalmic Liquid Solution) contains a preservative, (b) (4). Your firm has not tested the preservative content in the batches at the time of release.

OBSERVATION 8

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug product conform to appropriate standards of identity, strength, quality and purity.

Specifically,

A. Your firm does not have a written procedure that describes the visual inspection process for sterile injectable products produced by your facility. Your firm does not perform 100% visual inspection, against a contrasting background for product contamination prior to distribution, such as HCG pre filled syringes.

B. Your firm failed to conduct any inspection to the extent possible for the presence of observable foreign and particulate matter for sterile ophthalmic preparations. For example on 12/14/2016, Pharmacist (b) (6), (b) (7)(C) stated that the firm does not have a written procedure for visual inspection, but he uses (b) (4)

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(b) (4) for Meta PT Eye Drops Solution (Phenylephrine HCL 2.5%, Tropicamide 1% Ophthalmic Liquid Solution) eye drops, (b) (4)

OBSERVATION 9

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

Specifically,

We observed inconsistencies with the product storage conditions and Beyond Use Date used on the product label for Meta PT Eye Drops Solution (Phenylephrine HCL 2.5%, Tropicamide 1% Ophthalmic Liquid Solution). The firms used the following information on three lots of Meta PT Eye Drops:

i. Lot# 112716sb; Manufactured 11/27/2016; Expiration Date 12/27/2016; Storage: Refrigerated
ii. Lot# 121416jp; Manufactured 12/14/2016; Expiration Date 12/29/2016; Storage: Refrigerated
iii. Lot# 121416sb; Manufactured 12/14/2016; Expiration Date 12/28/2016; Storage: Room Temperature

Additionally, the samples that are on stability for this product are (b) (4) although the product distributed is labeled to be held under refrigerated conditions. Although there is analytical potency data from an external laboratory, the Certificate of Analysis (COA) states (b) (4) . The method(s) used for testing are not validated." Therefore, the firm does not have potency data to support the claimed shelf life/expiration dating of the finished product, listed above. Further, your firm stated that they are basing the expiration date on the proposed USP<797> refrigerated and room temperature BUD of 42 days. This proposed BUD is ongoing review and has not been finalized. The established <797> BUD is 3 days for refrigerated and 24 hours for room temperature.

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OBSERVATION 10

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

Specifically,

A. On November 26, 2016, Pharmacist (b) (6), (b) (7)(C) documented the temperature as 1°C, and indicated in the temperature log it was within the required specification of (b) (4) Also, there is no recording of temperature on November 24, 25, and 27, 2016. Your firm did not conduct an investigation for a temperature Out of Specification (OOS) for Bulk Drug Substances held in your cold storage refrigerator.

B. Your firm did not perform investigations for incidences where pharmacists entered the ISO 7 cleanroom inappropriately gowned.

C. Your firm did not conduct a investigations for incidences where Pharmacist S. B and Pharmacist (b) (6), (b) (7)(C) performed inadequate aseptic technique.

OBSERVATION 11

Batch production and control records do not include complete information relating to the production and control of each batch.

Specifically,

Compounding records that we reviewed did not include the actual drug substance or excipient lot number used to produce the drug product, detailed production instructions, and lacked a specimen label of the finished drug product.

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OBSERVATION 12

Examination of packaging and labeling materials for suitability and correctness before packaging operations is not performed and not documented in the batch production records.

Specifically,

Your firm does not have adequate controls for issuing labels, examining issued labels, and reconciliation of used labels. In addition, your firm does not have adequate controls to ensure proper identification of filled containers prior to labeling. For example, we observed Pharmacist (b) (6), (b) (7)(C) issue new labeling for the following lots without review or approval:

- Lot# 121416jp; Manufactured 12/14/2016; Expiration Date 12/29/2016; Storage: Refrigerated
- Lot# 121416sb; Manufactured 12/14/2016; Expiration Date 12/28/2016; Storage: Room Temperature

Also, your firm does not document an examination for accuracy of the label prior to release of the drug product.

OBSERVATION 13

Component testing is deficient in that each component is not tested for conformity with all appropriate written specifications for purity, strength, and quality.

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Specifically,

The following bulk drug substances used by your facility to produce drug products are not each accompanied by a valid certificate of analysis:

- Human Chorionic Gonadotropin (b) (4) (HCG), Lot # (b) (4)
- Folic Acid (b) (4) Lot # (b) (4)
- Levocetrizine Hydrochloride Lot # (b) (4)
- (b) (4) Lot # (b) (4)

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