DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612 (949) 608-2900 Fax:(949) 608-4417 Industry Information: www.fda.gov/oc/industry	08/31/2015 - 09/11/2015* FEI NUMBER 3005256616

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Justin Y. Chen, Pharmacist in Charge

FIRM NAME	STREET ADDRESS
Chen Shwezin, Inc. dba Park Compounding Pharmacy	280 N Westlake Blvd Ste 100
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Westlake Village, CA 91362-7014	Producer of Sterile Drugs

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

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.

Specifically,

Your firm's ISO 5 (b) (4) that was used to prepare sterile products was not well maintained. For example,

A. The ISO 5 (b) (4) was located in a non-classified room and the there were multiple holes and slots on the bottom plate of ISO 5 (b) (4) that were open directly to the non-classified environment, which may result in air exchanges between the ISO 5 and the non-classified environment.
B. There is no pest control and monitoring program at your firm.
C. The pressure differential between ISO 5 (b) (4) and the non-classified room was not monitored.
D. There was an area of brownish stain on the floor below the ISO 5 (b) (4)
E. Peeled paint was observed on the wall in the vicinity of the ISO 5
F. The inside of the ISO 5 (b) (4) was cluttered with various supplies, such as (b) (4) stoppers (b) (4) bottles, wipers (b) (4) and various reagents.
G. A (b) (4) of the ISO 5 (b) (4) and the (b) (4) The (b) (4) (b) (4)
H. The ISO 5 (b) (4) has many crack marks on wall.
I. The (b) (4) inside the far left of ISO 5 (b) (4)
J. Multiple stains were observed inside the ISO5 (b) (4)
   i. Numerous brownish colored stains were observed on the back wall and on the right side HEPA filter grid.
   ii. Numerous brownish colored stains were observed on top of a (b) (4)
   iii. Numerous white colored stains were observed on the front panel.
   iv. Two white colored droplets were seen on the left side HEPA filter grid.
   v. Dark spots were observed on the horizontal metal bar on the back wall.

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OBSERVATION 2

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

Specifically,

A. The firm has not validated the sterilization (b) (4) used to sterilize beakers, bottles, vials, and stoppers. There was no evidence established that the choser(b) (4) is appropriate to remove endotoxins. The beakers, bottles, vials, and stoppers are used for the preparation of sterile products such as Methylcobalamin, Prostaglandin PGE-1, and Tri-Mix.

B. During the sterilization of containers/closures used for your firm's sterile products, no(b) (4) was used to verify the effectiveness of the sterilization(b) (4)

C. The process of aseptic preparation for your sterile drug products was validated through media fill study. However, your media fill study was deficient in that,

   i. There was no detail recorded other than a simple table with check marks. For example, there was no record of weight used to prepare the media; no record of containers/closures used in the process; and no record of time span for the entire process.

   ii. Your firm's media fill study used (b) (4) and procedure provided by(b) (4). The process and containers/closures described in (b) (4) did not represent the worst case of your sterile product preparation process. According to PIC, the media fill process took about(b) (4) to complete. However, the actual preparation process of Methylcobalamin sterile product takes about(b) (4) .

   iii. According to media fill instruction on page 133 of(b) (4) , the media samples should be incubated at (b) (4) Your firm incubated the media samples at (b) (4) (b) (4)

D. The PIC stated that all finished products were visually inspected. However, no procedure was established requiring 100% visual inspection of the finished product and there was no documented evidence that the visual inspection was actually carried out.

E. During the preparation of Tri-Mix product lot 09012015@4 on 01Sep2015, the following deficiencies were observed,

   i. The pharmacist (b) (6) brought in a Prostaglandin (b) (4) into the ISO 5 (b) (4) without having the(b) (4) container wiped down with disinfectant first and a section of her forearm skin was exposed without any protection.

   ii. The same(b) (4) was then transferred (b) (4) by PIC without having the container being wiped down.

   iii. After transferring the non-sterile API drug (b) (4) (Phentolamine and Papaverine HCl)(b) (4) the (b) (4) amount of APIs was left open on the work bench of ISO 5(b) (4) throughout the remaining course of product preparation. A partially opened pouch containing (b) (4) b) (4) (b) (4) vials was in the vicinity of this (b) (4)

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OBSERVATION 3

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

Specifically,

A. Your firm failed to conduct environmental monitoring of air and surface for viable and non-viable inside the ISO 5 (b) (4) during the days when your sterile products were prepared.
B. Your firm's (b) (4) ISO 5 (b) (4) surface monitoring of viable was deficient in that the sampling plan was not established and the (b) (4) (b) (4) used for sampling was not verified with growth promotion test.
C. The incubation duration for (b) (4) surface monitoring samples were not handled according to (b) (4) use instruction. The (b) (4) instructs to incubate the plates at (b) (4) your firm incubated the plates (b) (4)
D. Your firm conducts (b) (4) cleaning of ISO 5 (b) (4) However, no documented evidence was established on how long it takes for the (b) (4) to restore to the ISO 5 condition. Per PIC, the (b) (4) can be used as soon as the (b) (4) cleaning is done.

OBSERVATION 4

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

Specifically,

A. Your firm performs (b) (4) cleaning and disinfecting the ISO 5 (b) (4) using (b) (4) However, the (b) (4) and the spray bottles were not sterile.
B. A (b) (4) with lot number (b) (4) was found in the ISO 5 (b) (4) room that had an expiration date of 2012-06. Per PIC, the firm was not using this expired disinfectant. However, there was no other bottle of (b) (4) available at the firm. According to firm's (b) (4) cleaning record, the (b) (4) was used since 2013 to present.
C. The wipers (b) (4) used for work bench cleaning (b) (4) and for wiping down tools, containers, and any items that are transferred from (b) (4) were not sterile.
D. No sporicidal agent was used for ISO 5 (b) (4) and room cleaning and disinfection.

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OBSERVATION 5

Drug products do not bear an expiration date determined by appropriate stability data to assure they meet applicable standards of identity, strength, quality and purity at the time of use.

Specifically,

The beyond use date (BUD) of your firm's products listed below were not supported by stability studies.

Sterile Products	Storage	BUD
Methylcobalamin Preservative Free (multiple strength)		
(b) (4)		6 M
Patient specific prescription with specific amount	Refrigerator	1 M
Methylcobalamin with Preservative (multiple strength)	Refrigerator	6 M
Prostaglandin PGE-1 with Preservative (multiple strength)		
(b) (4)		6 M
Patient specific prescription with specific concentration	Refrigerator	1 M
Tri-Mix with (b) (4) as Preservative (multiple strength)	Refrigerator	1 M
Prostaglandin – Phentolamine with Preservative (multiple strength)	Refrigerator	1 M
Phentolamine – Papaverine With Preservative (multiple strength)	Refrigerator	1 M
Caffeine+Sodium Benzoate Preservative Free 500 mg/mL Office Use	RT	3 M

Methylcobalamin Preservative Free 20 mg/mL (b) (4) and Prostaglandin PGE-1 500 µg/mL (b) (4) were used (b) (4) for patient specific prescription preparations with (b) (4) the stoppers. According to PIC, the BUDs for the products listed above were established by (b) (4) However, you firm had never conducted any stability studies to establish the evidence that the products maintain their identity, strength, quality and purity throughout the claimed BUDs, especially for the (b) (4) where stoppers (b) (4) during the storage period.

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OBSERVATION 6

Container closure systems do not provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product.

Specifically,

A. Storage of sterilized stoppers and vials may pose contamination risks. Previously sterilized stopper and vials used as container closure for your sterile products were initially stored in (b) (4) However, there were no expiration dates for these pre-sterilized items. According to the PIC, these items can be continuously used until they are consumed. (b) (4) of stoppers and vials with date of 7/8/2015 and 7/9/2015 were stored (b) (4) The (b) (4) containing dozens of sterilized vials were partially open during the course of Tri-Mix product lot 09012015@4 preparation on 01Sep2015. At the end of product preparation, the (b) (4) (b) (4) Per PIC, these (b) (4)

B. Your firm did not perform container closure integrity test to ensure that the chosen container closure would provide adequate protection to the sterile products. At the end of Tri-Mix product lot 09012015@4 preparation, no container closure integrity test was performed.

OBSERVATION 7

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically,

Your firm's ISO 5 (b) (4) was certified (b) (4) by an outside contractor (b) (4) The (b) (4) certification included smoke study. However, the smoke study was only conducted at static condition. No dynamic smoke study was carried out to evaluate the air flow pattern during the actual use.

OBSERVATION 8

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

Specifically,

A. Your firm tests sterility and endotoxin for (b) (4) sterile products. However, endotoxin limits for these (b) (4) were not established.

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B. Your (b) (4) (Methylcobalamin and Prostaglandin PGE-1) were assigned 6 month BUD. (b) (4) were tested for sterility and endotoxin at the time of (b) (4) (b) (4) individual patient specific drug products. There is no assurance that the sterility and endotoxin levels of the (b) (4) remain within the acceptable limit after repeated use.

OBSERVATION 9

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

Specifically,

There is no procedure established for the equipment calibration. Your firm has not calibrated following critical equipment.

A. The (b) (4) thermometers used to monitor the temperature of your only (b) (4) (with brand (b) (4)) for sterile product (Methylcobalamin and Prostaglandin PGE-1) storage.
B. (b) (4) used for sterile (b) (4)
C. Incubator used for samples taken from (b) (4) surface monitoring of ISO 5 (b) (4)

OBSERVATION 10

The separate or defined areas necessary to prevent contamination or mix-ups are deficient.

Specifically,

The large room outside the ISO 5 (b) (4) room was considered by your firm as general room where food items, microwave oven, and cook wares are stored in open place. This area also serves as break room for employees to take snacks and lunches. However, an (b) (4) was also placed in the same room where containers and closures were sterilized. In addition, the (b) (4) was stationed right next to a bathroom. During our inspection on 31Aug2015, we noticed that the bathroom door was left partially open for at least 3 hours.

*** DATES OF INSPECTION:**
08/31/2015(Mon), 09/01/2015(Tue), 09/02/2015(Wed), 09/03/2015(Thu), 09/08/2015(Tue), 09/11/2015(Fri)

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration

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Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."