

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303) 236-3000 Fax: (303) 236-3100 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 3/26/2018 - 4/4/2018*
	FEI NUMBER 3007816026

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Paul V. Vasiliauskas, President

FIRM NAME Vitalab Pharmacy, Incorporated (dba Vasco Pharmacy)	STREET ADDRESS 4045 E. Bell Road, Suite 163
CITY, STATE AND ZIP CODE Phoenix, AZ 85032	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile and Non-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 (I) (WE) OBSERVED:

OBSERVATION 1:
 You had inadequate HEPA filter coverage and airflow over the area which sterile product was exposed.


Specifically, your firm's (b) (4) [redacted] laminar airflow hood, located in the non-hazardous buffer room, does not provide sterile-filtered air moving at the same speed and in the same direction with no or minimal cross-over of air streams to the aseptic processing surface, as demonstrated by your most recent smoke study evaluation conducted on 11/14/2017.

Current products aseptically produced in this hood are: TriMix, Methylcobalamin, and Methionine/Inositol/Choline/B12.

OBSERVATION 2:
 Disinfecting agents and cleaning wipes used in the ISO 5 classified aseptic processing areas were not sterile.

Specifically, your firm utilizes non-sterile, 12"x12" clean room wipes, to disinfect the ISO 5 classified aseptic processing area, to disinfect materials introduced into the ISO 5 work space, and as a placemat to rest sterile items placed on the ISO 5 work surface.

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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Zachery L. Miller, Drug Specialist CSO	DATE ISSUED 04/04/2018
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OBSERVATION 3:
 Personnel engaged in aseptic processing were observed with exposed upper face.

Specifically, your firm does not use a full-face plate during aseptic processing that addresses exposed eyes/eye orbital area. On 3/28/18, I observed your technician's head enter the (b) (4) laminar flow hood by four to six inches, underneath the glass shield, exposing his face to the HEPA filtered air while he was sanitizing rubber stoppers of vials and the neck of ampules with Sterile (b) (4) prior to the introduction of a (b) (4) (b) (4).


OBSERVATION 4:
 Media fill studies are not conducted to closely simulate aseptic production operations.

Specifically, a media fill or process simulation has not been performed for all your aseptically prepared formulations. For example, a media fill has not been performed for your highest volume, most manually intensive, and most exposed formulation, (b) (4).

OBSERVATION 5:
 Personnel manually contacted the inner surface of the container closure during aseptic production.

Specifically, during aseptic processing on 3/27/18, I observed your technician hand stoppering vials with her left hand while filling vials with her right hand. During this process, the technician's hand came into contact with the inner surface of one of the stoppers. The product involved was C-Progesterone 50mg/mL in Ethyl Oleate Injection.

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***DATES OF INSPECTION**
 3/26/2018(Mon), 3/27/2018(Tues), 3/28/2018(Wed), 3/29/2018(Thu), 3/30/2018(Fri), 4/2/2018(Mon), 4/3/2018(Tues), 4/4/2018(Wed)

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