

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER Denver District Office 6th Avenue and Kipling Street, Building 20 Denver, CO 80225 303-236-3017 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 07/22/19-08/02/19
	FEI NUMBER 3007816026

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Kristine A. Lowe, Pharmacist in Charge (PIC)

FIRM NAME Vitalab Pharmacy, Inc., DBA Vasco Rx Specialty Pharmacy	STREET ADDRESS 4045 East 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

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

Specifically, production personnel use (b) (4) to produce all non-sterile oral solutions and suspensions which contain (b) (4). Your firm does not assess microbial or (b) (4) of (b) (4). Production personnel used (b) (4), lot (b) (4) to produce more than 50 finished products including Miracle Mouthwash, lot 07092019@146; and Potassium Bromide, lot 07192019@153.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Nicholas L. Hunt, Investigator	DATE ISSUED 08/02/2019
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