

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
DISTRICT ADDRESS AND PHONE NUMBER 1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510) 337-6700 Fax: (510) 337-6702		DATE(S) OF INSPECTION 10/24/2018-10/29/2018* FEI NUMBER 3012327563
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Raymond P. Jajeh, Owner/ Pharmacist in Charge		
FIRM NAME Jajco, Inc. DBA Anchor Drugs Pharmacy	STREET ADDRESS 161 S Spruce Ave	
CITY, STATE, ZIP CODE, COUNTRY South San Francisco, CA 94080-4517	TYPE ESTABLISHMENT INSPECTED Producer of Non-Sterile Drug Products	
<p>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.</p>		
<p>DURING AN INSPECTION OF YOUR FIRM WE OBSERVED: OBSERVATION 1</p> <p>You produced hazardous drugs without providing adequate cleaning of work surfaces and cleaning of utensils to prevent cross-contamination.</p> <p>Specifically,</p> <p>Your firms cleaning of utensils, equipment, and work surfaces is inadequate. Your firm uses (b) (4) (b) (4) to mix drug substance including testosterone and estradiol. This type of glassware is cleaned in a dishwasher using store bought detergent. Your firm also uses dish soap and lint free wipes to clean the encapsulation equipment and (b) (4) Your firm does not use dedicated equipment for hazardous drugs and your cleaning process is inadequate to prevent cross-contamination.</p>		
<p>OBSERVATION 2</p> <p>Non-microbial contamination was observed in your production area.</p> <p>Specifically,</p>		
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Farhana Khan, Investigator Ashar P Parikh, Investigator	DATE ISSUED 10/29/2018
	<small>Ashar P Parikh Investigator Signed by Ashar P. Parikh -S Date Signed 10-29-2018 14:51:47</small> X	
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATIONS
		PAGE 1 of 2 PAGES

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510) 337-6700 Fax: (510) 337-6702	<small>DATE(S) OF INSPECTION</small> 10/24/2018-10/29/2018*	
<small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small> Raymond P. Jajeh, Owner/ Pharmacist in Charge		
<small>FIRM NAME</small> Jajco, Inc. DBA Anchor Drugs Pharmacy	<small>STREET ADDRESS</small> 161 S Spruce Ave	
<small>CITY, STATE, ZIP CODE, COUNTRY</small> South San Francisco, CA 94080-4517	<small>TYPE ESTABLISHMENT INSPECTED</small> Producer of Non-Sterile Drug Products	
<p>While observing production of Tylosin 50mg capsules and Trilostane 35mg/ml solution in your firm's (b) (4) hood, we observed powder residue built up on the sides of the (b) (4) and the three clips used to hold the (b) (4) (b) (4) in place. Your firm does not clean these areas as part of your routine cleaning operations. This (b) (4) hood is used to compound non-sterile human and animal drugs as well as hazardous drugs including but not limited to testosterone and estradiol.</p>		
<p>*DATES OF INSPECTION 10/24/2018(Wed), 10/25/2018(Thu), 10/29/2018(Mon)</p>		
<div style="border-bottom: 1px solid black; width: 150px; margin-left: 0;"> Farhana Khan Investigator Signed By: 1300172865 Date Signed: 10-29-2018 14:52:32 X </div>		
<p>SEE REVERSE OF THIS PAGE</p>	<small>EMPLOYEE(S) SIGNATURE</small> Farhana Khan, Investigator Ashar P Parikh, Investigator	<small>DATE ISSUED</small> 10/29/2018
<div style="border-bottom: 1px solid black; width: 150px; margin-left: auto;"> Ashar P Parikh Investigator Signed By: Ashar P. Parikh -S Date Signed: 10-29-2018 14:51:47 X </div>		