

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
DISTRICT ADDRESS AND PHONE NUMBER 10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax: (973) 331-4969		DATE(S) OF INSPECTION 8/19/2019-8/28/2019* FEI NUMBER 3008876196
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Robert Keem, General Manager		
FIRM NAME Athenex Pharma Solutions, LLC	STREET ADDRESS 11342 Main St	
CITY, STATE, ZIP CODE, COUNTRY Clarence, NY 14031-1718	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility	
<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 I OBSERVED: OBSERVATION 1 Written production and process control procedures are not followed in the execution of production and process control functions.</p> <p>Specifically,</p> <p>A. The firm's SOP No. APS-SOP-0344 "503B Bulk Formulation-(b) (4) and Sealing Process" states to wipe down all work surfaces and equipment with a clean room wiped that has thoroughly wetted with (b) (4). However, on 08/20/2019 during the manufacturing of Norepinephrine 1mg/ml, Lot# S1900185, an operator was observed not wiping down all work surfaces and equipment with a clean room wipe that has been thoroughly wetted with (b) (4)</p> <p>B. The firm's SOP No. APS-SOP-0308 "503B Syringe Compounding Aseptic Process" states to wipe the top seams around the raw syringe container with a (b) (4) cloth. Wipe top of the container (b) (4) Wipe bottom of the container (b) (4) making sure to get into crevices. Wipe all four sides of container (b) (4) Rotation of the container may be done for better angles to wipe. However, on 08/23/2019 during the manufacturing of Neostigmine Methylsulfate 5mg/5ml syringe, Lot # F1900899, an operator was observed wiping the bottom of the container (b) (4) with the (b) (4) cloth during drug production in the ISO 5 classified area.</p>		
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Tonia F Bernard, Investigator	DATE ISSUED 8/28/2019
		Tonia F Bernard Investigator Signed By: 2001637553 Date Signed 08-28-2019 14:36:59 X

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***DATES OF INSPECTION**

8/19/2019(Mon), 8/20/2019(Tue), 8/21/2019(Wed), 8/22/2019(Thu), 8/23/2019(Fri), 8/26/2019(Mon), 8/28/2019(Wed)

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