

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

DISTRICT ADDRESS AND PHONE NUMBER

US Customhouse Rm900 200 Chestnut St
Philadelphia, PA 19106
(215) 597-4390 Ext:4200 Fax: (215) 597-0875
ORAPHARM1_RESPONSES@fda.hhs.gov

DATE(S) OF INSPECTION

6/21/2022-7/8/2022*

FEI NUMBER

3005117563

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mr. Rahul Sareen, Corporate Head of Quality

FIRM NAME

KVK-Tech, Inc.

STREET ADDRESS

110 Terry Dr

CITY, STATE, ZIP CODE, COUNTRY

Newtown, PA 18940-3427

TYPE ESTABLISHMENT INSPECTED

Drug Manufacturer

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: AMENDMENT 1

FACILITIES & EQUIPMENT SYSTEM

OBSERVATION 1

Buildings used in the manufacturing, processing, packing and holding of a drug product are not maintained in a good state of repair.

Specifically, the manufacturing facility is not maintained adequately to protect the quality, purity, strength, and identity of the finished drug products manufactured at the site. For example:

A. Between February 2021 to February 2022, you reported following fifteen (15) incidents when the water leak was detected inside the facility that impacted GMP manufacturing areas and or equipment.

No.	Roof Leak Occurrence Date	Impacted GMP Areas
1	02/25/2021	Suite # 10
2	05/27/2021	Suite # 6
3	06/07/2021	Manufacturing hallway between (b) (4) Room and Suite # 20
4	06/12/2021	Suite # 30

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EMPLOYEE(S) SIGNATURE

Saleem A Akhtar, Investigator
Monika Borkowska, Investigator
Jose M Cayuela, Investigator - Dedicated Drug Cadre

 Saleem Akhtar
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Date: 2022.07.12 11:40:12 -0400

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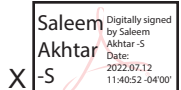
Drug Manufacturer

5	07/12/2021	Suite 10, Suite 14, Hallway outside Suite 21, Hallway outside Suite 14, Washroom, Laboratory Area
6	07/26/2021	Suite 29
7	08/08/2021	Manufacturing Hallway between (b) (4) room and Suite #20
8	08/10/2021	Corridor outside Suite # 28, Packaging Washroom, Corridor outside Suite # 15, Corridor outside Suite # 11
9	08/22/2021	Suite # 15 and # 26 Hallway
10	09/1/2021	Corridor outside Suite # 27 /28, Packaging Washroom, Corridor outside Suite # 15, (b) (4) room # 12, Warehouse, Outside corridor of room #20, (b) (4) # 14, (b) (4) # 13, DEA vault door, Boiler room front of room #20, (b) (4) room #26, (b) (4) room #21, Main manufacturing entrance
11	09/10/2021	Manufacturing hallway outside Suite #15
12	10/25/2021	Suite #29
13	10/26/2021	Electrical Room (between Suite #29 and Suite #26), Suite #29 and (b) (4) Room outside of Suite #28
14	01/17/2022	(b) (4) Room Suite # 25 and Suite # 27
15	02/18/2022	Suite # 27

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You failed to implement effective corrective actions during these repeated incidents. For example, during February 2021 to February 2022 there were fifteen (15) incidents when water leak (mostly from rain) was observed in the GMP areas. During this time, the firm manufactured more than (b) (4) commercial batches in this facility.

Between the dates of August 8, 2021, to September 10, 2021; there were five instances of roof leaks impacting approximately 20 areas during commercial manufacturing of finished drug products intended for the U.S. market. During these days, you manufactured following drug products in this facility.

No.	Product Name	# of Batches
1	(b) (4)	(b) (4)
2	CYCLOBENZAPRINE HCL TABLETS USP 10 MG	(b) (4)
3	CYCLOBENZAPRINE HCL TABLETS USP 5 MG	
4	DIETHYLPROPION HCL TABLETS USP 25MG	
5	(b) (4)	
6	(b) (4)	
7	(b) (4)	
8	(b) (4)	
9	HYDROXYZINE HYDROCHLORIDE TABLETS, USP 50 mg	

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10	(b) (4)	(b) (4)
11	(b) (4)	(4)
12		
13		
14		
15		
16	PHENTERMINE HYDROCHLORIDE CAPSULES, USP 30 mg	
17	PHENTERMINE HYDROCHLORIDE CAPSULES, USP 37.5 mg	
18	PHENTRAMINE HCL INTERMEDIATE BEADS 106MG/GM	
19	PHENTRAMINE HCL TABLETS USP 37.5MG	
20	PROMETHAZINE HYDROCHLORIDE TABLETS, USP 25 mg	
21	SODIUM POLYSTYRENE SULFONATE, USP Powder 15 g/bottle	
22	SODIUM POLYSTYRENE SULFONATE, USP Powder 454 g/bottle	
23	(b) (4)	
Total		

You did not perform any additional testing on most of these released batches to evaluate if these water leaks potentially impacted the product quality.

B. On 9/1/2021, bulk drug (b) (4), batch (b) (4) was being packaged in Process Room (b) (4) when the water from the roof started leaking inside the room due to

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hurricane IDA. During this storm, the water leak was observed in most of the GMP areas including Corridor outside Suite # 27 /28, Packaging Washroom, Corridor outside Suite # 15, (b) (4) room # (b) (4) Warehouse, Outside corridor of room #20, (b) (4) room # (b) (4) room # (b) (4) DEA vault door, Boiler room front of room #20, (b) (4) room (b) (4) room (b) (4), and Main manufacturing entrance.

The site had packaged (b) (4) bottles of (b) (4) when water started leaking about two feet from the (b) (4) (ID: MA 1441). The site halted the packaging operations in this room and removed opened, uncapped bottles as well as the bulk product (about (b) (4) was removed) from the hopper and returned to the bulk drug container, sealed, and removed from the packaging area to the vault. The site packaged the remaining batch on 9/9/2021 in the same room i.e., (b) (4) Room (b) (4) Major cleaning of the room and equipment was done on 9/2/2021. The room and equipment was not cleaned prior to packaging of the remaining portion of the batch on 9/9/2021. The site does not have scientific data to support that the room and equipment stays clean for seven days. The site did not reject any portion of the batch that might have been impacted by the water leak inside the packaging room. This batch (batch size: (b) (4) tablets) was released by testing the samples collected during compression stage (performed on August 25-31, 2021). The site performed micro analysis (not part of release specifications) of the packaged product; however, failed to test any packaged bottles of this batch (that might have been impacted by the leak) if it still meets the release specifications. This batch was not placed on stability to observe any potential impacts that the incident might have caused.

During an inspectional walkthrough of the same packaging room (Suite (b) (4) on 7/5/2022, a stain that appeared as a leak mark was observed on a ceiling tile right above the packaging line (next to re-torquer equipment). On 7/5/2022, (b) (4) batch (b) (4) was being packaged in this room.

C. Although the firm installed a new roof on the building in October 2021, the following deficiencies were observed during the inspection of the roof on 6/24/2022:

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- a. The roof design does not facilitate the drainage of rainwater. It rained on 6/23/2022 and on 6/24/2022 we observed too numerous to count water puddles on the roof. Most of these water puddles were found directly above GMP production areas.
- b. The roof of the maintenance workshop is about 5.5 feet above the facility's roof. We observed the gutter of the maintenance workshop roof was leaking and the leaking water was being collected on a (b) (4). This water was overflowing from this (b) (4) on to the facility's roof. We also observed a duct tape placed on the leaking gutter.
- c. We observed that the metal plumbing (supply and return) used to provide chilled water from Chiller (ID: MA-1963) to the various Air Handling Units (AHUs that provided filtered air to the GMP areas) was not insulated properly or the insulation was wearing off (more specifically for the AHU ID: MA1071 that is installed right above the manufacturing suites (b) (4)) causing the accumulation of condensate around the area. Some of these metal pipes on the roof that are exposed to the environment appeared to be corroded and rusted and a brown colored residue was observed at many locations on the roof.
- d. The condensate from the air handling units is collected in the (b) (4) pipes and moved toward the partially covered drainage collection area on the roof. We observed these (b) (4) pipes do not deliver the condensate directly into the drain. Instead, the water is discharged on the roof then it goes into the drain. At one location, we observed the draining area was clogged with debris and the water was accumulated around the area. On 8/8/2021 the site initiated a deviation DEV-2021-0192 when the drain that collects condensate from air handling unit (ID: MA-1083) was clogged with debris that caused water leakage from the ceiling tiles in the hallway next to manufacturing Suite (b) (4). No CAPA was initiated for this deviations.

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- e. We observed (b) (4) drain vent pipe (about (b) (4) feet high) was loosely held with the roof. The material that was used to seal this pipe with the roof appeared to be damaged from one location that can potentially cause the leakage of the rainwater into the facility. We observed a water puddle close to this pipe. Additionally, the portion of the roof color (originally white) appeared brown around this vent pipe. It appeared the rust was coming off from this pipe. This pipe is located above the boiler room that is connected with Suite 27 (compression room) and suite 29 (packaging room) through a hallway.

The facility had water leak in 2020 as well and the firm was cited for this deficiency during the previous inspection in June 2021.

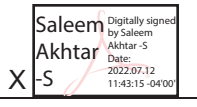
OBSERVATION 2

Written procedures are not established and followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically, the firm has not completed the cleaning validation studies for (b) (4) coating Pans (ID: (b) (4)) used to manufacture Phentermine HCl Capsules USP 30 mg, Phentermine HCl Intermediate Beads 106 mg/gm, Indomethacin ER Capsules 75 mg, Indomethacin Extended Release Intermediate Beads 267 mg/gm, and Chlorpheniramine Maleate Extended Release Tablets, 12 mg.

As per Cleaning Validation Protocol (PN-0644, Revision: 1, Effective Date: 1/19/2022), Chlorpheniramine Maleate ER Tablets is identified as the worst case product to clean for this shared equipment. The site has not completed (b) (4) cleaning runs as required under this validation protocol. So far, the site has completed one cleaning run in Jan 2022.

Since June 2020 until June of 2022, the firm has approximately manufactured following commercial batches by using these coating pans:

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Product Name	Number of batches
Phentermine HCl Capsules, 30 mg	(b) (4)
Phentermine HCl Intermediate Beads 106 mg/gm	
Indomethacin ER Capsules 75 mg	
Indomethacin Intermediate Beads 267 mg/gm	
Chlorpheniramine Maleate ER Tablets 12 mg	


Repeat observation from FDA-483-June 2021

OBSERVATION 3

Buildings used in the manufacture, processing, packing, or holding of a drug product do not have the suitable construction to facilitate cleaning, maintenance, and proper operations.

Specifically, the dispensing room (ID: Suite (b) (4)) does not have the suitable construction to facilitate cleaning, maintenance, and to prevent contamination. For example:

- A. During the inspection of the dispensing room (ID: Suite (b) (4)) on 6/21/2022, it was observed that a small portion of the room floor was covered with pieces of duct tape. The duct tape appeared to be torn, wearing off and missing pieces.
- B. The epoxy coating on the room floor appeared to be peeling off with chipping and missing pieces from too numerous to count surfaces.
- C. There was a table (appeared as (b) (4)) placed next to the (b) (4) scale in this room. Portion of this table and the adjoining floor appeared to have dark

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brown and black colored spots and buildup of unknown material.

Suite (b) (4) is the only dispensing room the firm is using to dispense excipients and active pharmaceutical ingredients (APIs) to manufacture finished drug products. Since June 2021, this room was used to manufacture more than (b) (4) batches of about 20 drug products.

QUALITY SYSTEM

OBSERVATION 4

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically, following investigations and deviations were not conducted thoroughly:

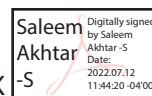
- A. The firm initiated the following fifteen (15) unplanned deviation investigations pertaining to the water leaks inside the GMP areas that were actively used to manufacture finished drugs:

No.	Deviation #	Occurrence Date
1	DEV-2021-0036	02/25/2021
2	DEV-2021-0116	05/27/2021
3	DEV-2021-0123	06/07/2021
4	DEV-2021-0129	06/12/2021
5	DEV-2021-0167	07/12/2021
6	DEV-2021-0183	07/26/2021
7	DEV-2021-0192	08/08/2021
8	DEV-2021-0197	08/10/2021

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9	DEV-2021-0207	08/22/2021
10	DEV-2021-0217	09/1/2021
11	DEV-2021-0223	09/10/2021
12	DEV-2021-0253	10/25/2021
13	DEV-2021-0254	10/26/2021
14	DEV-2022-0011	01/17/2022
15	DEV-2022-0039	02/18/2022

Most of aforementioned water leaks were investigated as separate incidents. In most cases the risk assessment was limited only to the area where water leak was detected and the manufacturing operations were resumed after cleaning of the impacted area.

Additionally, you detected extraneous and unknown peaks on 15 instances during commercial release and stability testing of the products manufactured in this facility.

No.	Investigation No.	Date Investigation was Initiated	Product Name	Batch No.	Stage	Test
1	INV-21-072	6/8/2021	(b) (4)	(b) (4)	24 M RT	Dissolution
2	INV-21-080	6/22/2021	(b) (4)	(b) (4)	Finished Product	Assay
3	INV-21-083	7/2/2021	Phendimetrazine Tartrate Tablets, USP	(b) (4)	3M RT	Dissolution

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			(b) (4)		
4	INV-21-091	8/12/2021		9M RT	Dissolution
5	INV-21-105	9/28/2021		48M RT	Impurity
6	INV-21-112	10/11/2021		Finished Product	Dissolution
7	INV-21-119	10/22/2021		Stability	Dissolution
8	INV-21-120	10/26/2021		Stability	Dissolution
9	INV-21-135	11/29/2021		Stability	Dissolution
10	INV-21-139	12/13/2021		Promethazine HCl Tablets, USP 25 mg	(b) (4) Stability Assay
11	INV-21-142	12/15/2021		Phendimetrazine Tartrate Tablets, USP 35 mg	(b) (4) 24M RT Dissolution
12	INV-21-146	12/29/2021		(b) (4)	Method Validation Residual solvent
13	INV-22-002	1/10/2022	36M RT Assay		

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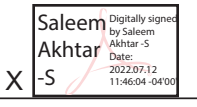
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CITY, STATE, ZIP CODE, COUNTRY Newtown, PA 18940-3427	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer

14	INV-22-019	2/11/2022	(b) (4)	3M RT	Dissolution
15	INV-22-047	4/21/2022	(b) (4)	6M RT	Dissolution

Incidents pertaining to the extraneous and unknown peaks were not thoroughly investigated to include all the possible factors that may cause these extraneous peaks. For example:

- a. Investigation INV-21-080 was initiated on 6/22/2021 when an extraneous peak eluting at retention time of (b) (4) minutes was observed in all samples during assay and content uniformity testing of (b) (4). For example, extraneous peaks having 0.17 and 2.4% were observed in stratified CU 1 and CU 8 samples. During the investigation no root cause was identified, and no laboratory error was observed. The batch was released concluding the extraneous peak is not related to the active ingredient i.e., (b) (4) and/or its degradants.
- b. Investigation INV-21-072 was initiated on 6/9/2021 when unknown peaks eluting at retention time of (b) (4) and (b) (4) minutes were observed during dissolution testing of (b) (4) (24-month long-term stability sample). The peak area from these unknown peaks was more than 2.0 % when compared to the main peak. During the investigation no root cause was identified, and no laboratory error was observed. The QC Lab accepted the original results concluding the unknown peaks did not interfere with the API peak.

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

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DATE(S) OF INSPECTION

6/21/2022-7/8/2022*

FEI NUMBER

3005117563

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mr. Rahul Sareen, Corporate Head of Quality

FIRM NAME

KVK-Tech, Inc.

STREET ADDRESS

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CITY, STATE, ZIP CODE, COUNTRY

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TYPE ESTABLISHMENT INSPECTED

Drug Manufacturer

- B. On 11/19/2021, a laboratory chemist reported the Assay-1 value of (b) (4) as 98.2% for the drug product (b) (4). The laboratory chemist documented the result as “Complies” and a quality assurance personnel reviewed the calculation and confirmed the result as ‘Complies’. However, we noted that the analyst used a wrong number in the formula and reported the complying correct assay result i.e., 98.2%. During the inspection, the Associate Director of the laboratory re-calculated the above assay using a calculator and the same formula and numbers obtaining an assay result of 5.114035%. However, using the correct number and formula, the assay value was 98.2%. The firm determined that the laboratory chemist performed an error in writing the calculations that was not detected by the quality assurance reviewer. The above error was subsequently recalculated in other page of the laboratory notebook without any investigation, corrective action, or preventive action. It was noted that:
- a. The Quality Unit failed to re-train/re-instruct the laboratory chemist and the quality assurance reviewer to avoid the recurrence of this calculation, documentation, and review error.
 - b. The Quality Unit failed to investigate and determine which other test results and drug products are also impacted by erroneous calculations, documentation, and reports performed by this laboratory chemist and by the quality assurance reviewer.

OBSERVATION 5

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically, the quality unit failed to perform its responsibilities as listed in SOP-0019, “Responsibilities of the Quality Control Unit”. For example:

- A. The Quality Unit failed to ensure the facilities and buildings used to manufacture commercial

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FOOD AND DRUG ADMINISTRATION**

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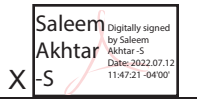
drug products are adequately maintained to prevent contamination.

- B. The Quality Unit failed to conduct thorough investigations & deviations pertaining to the a) water leakage in the GMP areas and b) extraneous/unknown peaks observed in the commercial batches. The scope of most of these deviations was limited to the specific area/batch and was not extended to the other batches manufactured during that time.
- C. The Quality Unit failed to thoroughly investigate the musty and moldy smell reported by the consumers in the finished drugs manufactured at the site. The firm failed to develop and establish a scientific test procedure or method for the detection and or evaluation of musty and moldy smell.
- D. Additionally, the responsibilities pertaining to the alarm notification generated from (b) (4) stability chambers regarding temperature and relative humidity excursion are not in writing. The alarms pertaining to the temperature and relative humidity excursions are managed by the third party service provider. The site does not have a technical quality agreement with the service provider for alarm notifications.

OBSERVATION 6

Procedures describing the handling of written and oral complaints related to drug products are deficiently written or followed.

Specifically, the firm failed to thoroughly investigate the consumer complaints as per SOP-0028, "Product Complaints for Quality and ADEs" pertaining to the odd smell coming out the products manufactured at the site. Between May 2019 to April 2022, the firm received about thirteen (17) complaints reporting odd smell including musty and moldy smell coming from various products such as (b) (4), Methylphenidate HCl Tablets, Promethazine HCl Tablets, Sodium Polystyrene Sulfonate Powder; Butalbital, Acetaminophen, and Caffeine, USP Tablets; and Phentermine

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HCl Tablets. The Quality Unit failed to implement appropriated corrective and preventive actions and to develop and establish a scientific test procedure or method for the detection and or evaluation of musty and moldy smell in drug products.

PRODUCTION SYSTEM

OBSERVATION 7


The batch production and control records are deficient in that they do not include documentation of sampling performed.

Specifically, the sampling activities performed during the manufacturing of Phentermine HCl Capsules are not documented on the executed batch record. For example:

During the review of the executed batch record of Phentermine HCl Capsules, USP 15 mg, batch (b) (4); it was observed that the section 50 of the Master Batch Record (MF# 026216, Effective Date: 7/30/2020) requires quality assurance to collect samples distributed evenly throughout the encapsulation run for submission to the quality control lab. These samples are used to make a composite sample that is used by the QC Lab for release testing. However, the time/date when these samples are collected are not documented in the batch record hence determination cannot be made if the sampling activity was performed at the defined intervals throughout the encapsulation run. There is no documented evidence to demonstrate that the composite sample is representative of the entire batch. The firm adopts same sampling practices for almost all the products manufactured at the site.

OBSERVATION 8

Rejected in-process materials are not identified to prevent their use in manufacturing or processing operations for which they are unsuitable.

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TYPE ESTABLISHMENT INSPECTED

Drug Manufacturer

Specifically, all rejected tablets by the metal detector during packaging of Methylphenidate Tablets were not reconciliated.

On 6/22/2022, we observed primary packaging of Methylphenidate HCl Tablets, 10 mg, batch (b) (4), 100 count in bottles in Suite 26. We observed the PLC display of the packaging machine was showing 6 bottles (100 tablets per bottle) were rejected by the metal detector. However, the rejection bin pertaining to the metal detector has only two bottles (200 tablets) in it. The firm could not account for the remaining rejected quantity i.e., 4 bottle (400 tablets). SOP-0350, "Process Flow and Inspection Procedure in Packaging Suite" restricts the re-bulking of the rejected product by the metal detector.

LABORATORY CONTROL SYSTEM

OBSERVATION 9

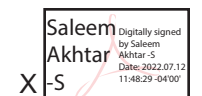
Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically, appropriate controls are not exercised over the electronic data generated by Ultra Performance Liquid Chromatographic Systems (UPLCs) in a way that chromatographic data is protected. Review of (b) (4) data from (b) (4) message center indicated seven (7) messages showing, "Ethernet cable was disconnected" pertaining to multiple (b) (4) projects. Additionally, there were four warning messages indicating, "DELETE FROM VIEWTEMPIDS WHERE VID = : VID". The data from (b) (4) message center is not reviewed and archived. The data from the (b) (4) message center gets deleted after (b) (4) automatically.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES
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OBSERVATION 10

The use of instruments and recording devices not meeting established specifications was observed.

Specifically, the (b) (4) Titrator (ID: INS/QC/445) used in the QC Lab failed to meet standardization specifications (such as (b) (4).) numerous times.


The entry on the equipment use logbook is made only when the equipment meets the standardization specifications. The QC Lab has not established how many failing standardizations would require preventive maintenance of the equipment. (b) (4) equipment audit trail records indicated the QC Lab analysts keep on performing the equipment standardizations until it meets the specifications and the incidents when it does not meet the specifications are not recorded on the equipment use logbook. For example, on 6/27/2020 the QC Lab analysts standardized the equipment four (4) times and recorded only two (2) entries when the equipment met the standardization specifications. The other two incidents, when the equipment failed to meet the standardization specifications, were not reported. This is the only instrument the firm has for water analysis in raw materials, finished products, and stability samples.

***DATES OF INSPECTION**

6/21/2022(Tue), 6/22/2022(Wed), 6/23/2022(Thu), 6/24/2022(Fri), 6/27/2022(Mon), 6/28/2022(Tue), 6/29/2022(Wed), 6/30/2022(Thu), 7/01/2022(Fri), 7/05/2022(Tue), 7/06/2022(Wed), 7/07/2022(Thu), 7/08/2022(Fri)

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