DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900 Fax:(973)331-4969 ORAPHARM1_RESPONSES@fda.hhs.gov	8/8/2022-8/18/2022* FEI NUMBER 3017532195

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Atul Mehta, President, Co-Chairman, Co-Founder	
FIRM NAME	STREET ADDRESS
Aarkish Pharmaceuticals NJ Inc	8 Commerce Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fairfield, NJ 07004-1602	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:

OBSERVATION 1

Batch production and control records for each batch of drug product produced do not include an accurate reproduction of the appropriate master production or control record which was checked for accuracy, dated and signed.

Specifically, you failed to maintain adequate document controls over exhibit batches for ANDA (b) (4) ((b) (4)).

Batch record discrepancies were noted in (b) (4) common blend, batch (b) (4) indicating that some of the original pages on the executed batch records were replaced with uncontrolled and altered copies of the approved MBR (MBR# (b) (4), and these discrepancies were confirmed by the firm's senior management. For example:

a. On page (b) (4) of batch records, V-Blender listed on the MBR identify "(b) (4) V-Blender" to be used in step (b) (4), while the executed exhibit batch record lists (b) (4). V-Blender" in the same step (b) (4)
b. Additionally, stamped batch number imprint on page (b) (4) of the executed batch record does not match the stamped imprints of other pages.

Note: This executed (b) (4) was used to produce (b) (4) Acetazolamide tablets (Batch# (b) (4)) and (b) (4) Batch# (b) (4)). Batch records with identified document discrepancies were submitted in the ANDA (b) (4) (b) (4)).

OBSERVATION 2

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	Junho Pak, Investigator Karen A Briggs, Investigator Jessica S Estriplet, Investigator	X Junho Pak Investigator Signed By 2000578589 Date Signed 08-18-2022 13 14 34	8/18/2022

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Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically, you have not established procedures for the following:

a. There are no written procedures or requirements to perform (b) (4) sanitization on the (b) (4) water (b) (4) distribution loop and there is no validated sanitization process for the (b) (4) distribution loop. Additionally, the (b) (4) system distribution loop has not been validated for system sanitizations and to maintain microbial controls. The firm's (b) (4) is generated and with (b) (4) generator with approximately (b) (4) external distribution loop, constructed with (b) (4) piping with one use point. The (b) (4) generator is set to (b) (4) circulate (b) (4) through the distribution loop at (b) (4) temperature, (b) (4) The (b) (4) from the distribution loop is used in the formulation of products, including (b) (4) steps for (b) (4), and (b) (4) steps for Varenicline and (b) (4).

b. Your written procedures do not contain instructions to review and verify all open Quality events are closed, prior to batch being released by the Quality Unit, including, deviations, OOSs, and CAPAs. Additionally, there are no procedures to identify conditionally released raw materials are fully released, prior to batch disposition. All finished product dispositions are conducted with SOP# RQA-008-00, "QA Approval or Rejection of Finished Products" using the (b) (4) The SOP RQA-008-00 do not contain verifications for open Quality events and open quality events are not included in the (b) (4).

OBSERVATION 3

Laboratory records do not include complete data derived from all tests, examinations and assay necessary to assure compliance with established specifications and standards.

Specifically, you failed to perform and document the following:

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a. During the review of the dissolution stability sample testing records for the PAI coverage product (b) (4), ANDA (b) (4)), there were no records to indicate (b) (4) equipment verification checks were performed on the identified dissolution apparatus for at (b) (4) dissolution testing. As per SOP RQC-032-00 (b) (4) dissolution apparatus verifications and checks are to be performed (b) (4) the dissolution apparatus conditions are (b) (4). This (b) (4) verification steps are documented on the (b) (4) The (b) (4) verification (b) (4) were not included within the analytical (b) (4) for at (b) (4) of (b) (4) Tablets from the ANDA exhibit batches, undergoing long term stability study.

b. Multiple sets of stability samples received into the QC laboratory were not documented in the stability sample receiving logbook. The following stability samples received into the laboratory were not documented in the (b) (4), including the following samples:

- (b) (4), batch (b) (4), and (b) (4) at (b) (4), sample pull date of 12/1/21.
- (b) (4) batch (b) (4), (b) (4) and (b) (4) at (b) (4), sample pull date of 3/1/22.
- (b) (4), batch (b) (4), sample pull date of 10/19/21.
- (b) (4) batch (b) (4) at (b) (4) sample pull date of 1/19/22.

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These stability sample result sets were submitted as part of the ANDA submissions and used to support the product expiry.

OBSERVATION 4

Failure to maintain a backup file of data entered into the computer or related system.

Specifically, your firm does not maintain full back ups of all original electronic data, generated by the analytical laboratory instrument. Generated analytical data from (b) (4) UV Spectrophotometer, Instrument ID# (b) (4) is not equipped to be saved or backed to retrievable storage media for review or verification. Currently, the only available analytical records from the analysis are the (b) (4) analysis reports, (b) (4) from the instrument. According to the QC Laboratory Manager, all analytical data is cleared from the instrument at the (b) (4), and there are no procedures to store generated electronic data.

Additionally, there are no data security controls in place on the (b) (4) UV-VIS Spectrophotometer instrument. During our review of the (b) (4) UV Spectrophotometer, Instrument ID# (b) (4), we observed demonstrations of sample results on the instrument could be deleted and/or modified, (b) (4) the final report. The ability to modify and delete data from current sample set was demonstrated on the instrument, with an analyst user role. As the electronic data is not retained, there is no means to verify for accuracy or completeness of the data on the (b) (4) reports, if the report was not (b) (4) or removed.

OBSERVATION 5

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.

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Specifically, you have not established data integrity security control measures on the HPLC software, (b) (4) and the software was not configured to restrict sample name changes on previously analyzed electronic data. During the review of the stored raw electronic data files on the (b) (4) (b) (4) we observed demonstrations on sample file name changes on previously analyzed sample runs and the modified sample names can be saved. The file name change demonstrations were performed by the QC manager, under Manager user access role. The firm's management stated that no laboratory personnel was given access privileges to rename sample names, including the Manager access roles.

Additionally, you do not have written instructions or requirements to perform audit trail reviews on the chromatography software, (b) (4). As a result, no audit trail reviews were required or performed to identity potential data file changes made on the (b) (4) system. Operational procedures for the HPLC system, including the (b) (4) software is contained in the SOP #RQC-028, "Operation Procedure of (b) (4) HPLC system (b) (4) This procedure is used to operate (b) (4) laboratory HPLC instruments and used to perform stability and finished drug product release testing.

OBSERVATION 6

Equipment for adequate control over air pressure and dust is not provided when appropriate for the manufacture, processing, packing or holding of a drug product.

Specifically, you failed to maintain manufacturing production rooms under (b) (4) (Specification: "(b) (4)") to prevent product cross contamination. According to SOP# RMF-007-01, production rooms are to be maintained at (b) (4) During the facility walkthrough on 8/8/22, we observed room differential pressure (b) (4) displaying (b) (4) readings for production rooms (b) (4) and (b) (4) and (b) (4) readings for several other production rooms. In room (b) (4), manufacturing operation was currently (b) (4) for (b) (4), batch# (b) (4).

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Additionally, each production room is equipped with exhaust vents (dust collectors), with (b) (4) dampers that can be opened and closed. Damper positions impact the (b) (4) in the manufacturing rooms, and open dampers create additional (b) (4) in in the production rooms. There are no written procedures for operations and handling of exhaust vents (dust collectors) and there are no procedures defining the damper positions during dynamic or static manufacturing conditions. During the facility walkthrough on 8/8/22, we observed the dampers in both open and closed positions. As per Mr. (b) (6) the damper positions may have contributed to some production rooms not maintaining (b) (4).

OBSERVATION 7

Drug products are not stored under appropriate conditions of temperature so that their identity, strength, quality, and purity are not affected.

Specifically,

a. You have not conducted seasonal (summer/winter) temperature mapping studies/qualifications for the (b) (4) temperature warehouse, to identify the worst-case locations to place (b) (4)). You have not documented a scientific rationale for the location of all (b) (4) which are placed only on one level, approximately (b) (4) off the ground, however, warehouse storage racks are at (b) (4) with materials observed to be stored on the top racks.

b. You failed to take actions to include documenting deviations and conduct investigations for multiple, repeated temperature excursions observed in the warehouse temperature monitors, and no impact assessments have been performed on the impacted products. Warehouse

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procedure (b) (4) states the warehouse temperature specifications of (b) (4) with allowed excursion conditions of up to (b) (4) However, during review of temperature monitoring records from June to July 2022, following was noted:

i. (b) (4) recorded temperature (b) (4)
ii. (b) (4) recorded temperature (b) (4))
iii. (b) (4) of the warehouse) (b) (4) and (b) (4)
iv. (b) (4) of warehouse) recorded (b) (4), and (b) (4)
v. Temperatures were recorded on (b) (4) and (b) (4) that exceeded (b) (4) and no deviations were initiated for temperatures exceeding excursion zone parameters (b) (4), currently stored in the warehouse, lists storage requirements of temperature not (b) (4) (b) (4), currently stored in the warehouse, lists storage requirement of (b) (4) (b) (4), currently stored in the warehouse, requires storage at room temp and (b) (4)

OBSERVATION 8

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

Specifically,

a. Manufacturing equipment was observed to have been cleaned and (b) (4). On

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8/8/2022, we observed (b) (4) in the production room (b) (4) documented to have been cleaned on (b) (4). Upon disassembly of the (b) (4) there was visible water trapped between the (b) (4) and the pan frame. The equipment cleaning procedure (b) (4) effective date (b) (4), states the (b) (4)

b. Equipment cleaning status are not identified with cleaning status labels/tags. In Room (b) (4) (Storage Room), we observed multiple items (e.g., buckets, sieve, scoops) identified to have been cleaned without (b) (4)" status card. The equipment are shared between all products and used in the manufacturing operations for dispensing/charging operations and used to transfer (b) (4) for production. According to SOP, RMF-006-00 Cleaning Procedure for Containers and Accessory Utensils Rev.00, effective Date 12/02/2020, (b) (4)" status must be attached to sanitized utensils.

OBSERVATION 9

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use and cleaning and maintenance.

Specifically, your firm does not have maintenance or work order procedures to report and make necessary repairs on equipment used for drug product manufacturing. On 08/08/2022, we observed the following equipment maintenance issues:

a. Your equipment operating procedure for (b) (4), equipment (b) (4), do not require (b) (4) replacement of exhaust vent filters on (b) (4) or during (b) (4). According to your SOP #RMF-037-00, and the (b) (4) (b) (4) is

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performed on filters (b) (4). There are no filter replacement frequencies or requirements Additionally, the (b) (4), does not have redundant controls to prevent backflow of product residues from previously manufactured product. The exhaust vent is not equipped with particle trap/bends in the exhaust piping and there are no additional filters installed on the equipment (i.e. outlet opening of the equipment.

On 8/13/21, product cross-contamination was identified on the (b) (4) for (b) (4) and (b) (4) (Lot (b) (4), contaminated with previously manufactured drug product on the (b) (4). This resulted in manufacturing deviation (b) (4). The investigation concluded the product contamination was due to system backflow from the exhaust vent/filter, and (b) (4).

b. In Room (b) (4) (Compression Room), the equipment access door to the Tablet Press machine ((b) (4)) was observed with malfunctioning door closure and operating with access door in open position. The door has a label that states, "Do Not Open Door When Machine Is In Motion". After management asked the operators to close the equipment's door, the staff members complied however the door reopened. Mr. (b) (6) explained that the door has difficulty staying closed due to the wires within the equipment. (b) (4) Batch #(b) (4), was being manufactured during that time of the observation. With the door remaining open during production, we observed visible white dust on the exterior equipment surfaces of the tablet compression machine and on the floor surfaces of the production room (b) (4)

c. In Room (b) (4), we observed visible gaps on the equipment frames and floor brackets, underneath the (b) (4) V -Blender, equipment (b) (4). The gaps were observed with trapped water,

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leaking out to form a puddle under the equipment. Rust like discoloration was observed on the gaps of the equipment, and brown, rust colored liquid was observed leaking out of the gaps to form a pool under the equipment. According to Mr (b) (6), the cleaning liquid/water during the equipment cleaning is drained out the bottom of the V-blender, directly to the floor drain.

d. In Room (b) (4) (Compression Room), we observed leaked and pooled oil on the inside of (b) (4), equipment (b) (4) just under the compression turret. Additionally, the (b) (4) were observed to be deteriorated and worn-out. According to Mr. (b) (6) the equipment leaks oil when the equipment is cleaned and not being used for production. (b) (4), Batch (b) (4) on (b) (4), was last manufactured on this equipment. The equipment was last cleaned on (b) (4) (b) (4) (ANDA (b) (4)) has been manufactured on this equipment; it was last manufactured on (b) (4)

e. In Room (b) (4) Blending Room), we observed equipment (b) (4) V-Blender with exposed electrical wires with outlet plug removed. Firm's management stated work was initiated to connect the equipment directly to a power junction box. Management confirmed that neither a work-order nor change control was created for the work. In addition, there was no label on the equipment that indicating equipment was placed out-of-order.

f. In Room (b) (4) (Stability Chamber Room), we observed water being drained into the drip tray of the stability chamber, equipment (b) (4) with visible water pooling on the tray and rust-like discoloration. The connected equipment tray drain was not functioning, and the pooled water did not drain. In addition, additional drain hoses for the doors were not ported outside the stability chamber and the drain hoses were observed to be pinched, when the chamber door

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was closed.

***DATES OF INSPECTION**

8/08/2022(Mon), 8/09/2022(Tue), 8/10/2022(Wed), 8/11/2022(Thu), 8/12/2022(Fri), 8/15/2022(Mon), 8/16/2022(Tue), 8/17/2022(Wed), 8/18/2022(Thu)

X Karen A Briggs
Investigator
Signed By: Karen A. Briggs -S
Date Signed: 08-18-2022 13:15:20

X Jessica S Estriplet
Investigator
Signed By: Jessica S. Estriplet -S
Date Signed: 08-18-2022 13:16:02

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."