DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857 ORAPHARMInternationalresponses@fda.hhs.gov	08/26/2024-09/06/2024
	FEI NUMBER 3004097901

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Anil Arora, President - Global Manufacturing Operations

FIRM NAME	STREET ADDRESS
Granules India Limited	Survey No 160/A, 161E, 162 And 174/A, Gagillapur Village, Dundigal-Gandimaisamma Mandal
CITY, STATE, ZIP CODE, COUNTRY Medchal-Malkhajgiri District, Telangana, 500043 India	TYPE ESTABLISHMENT INSPECTED Drug Product 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:

FACILITY AND EQUIPMENT SYSTEM

OBSERVATION 1

Equipment and utensils are not cleaned at appropriate intervals to prevent that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

A. The (b) (4) non-dedicated (b) (4) used in the manufacturing of drug products at your firm have not been appropriately cleaned since their installation several years ago. For example,

Table 1

(b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Pratik S. Upadhyay, DDC Investigator Joseph A. Piechocki, Investigator	09/06/2024

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Medchal-Malkhajgiri District, Telangana, 500043 India	Drug Product Manufacturer

(b) (4)

[redacted]

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(b) (4)

On 26-Aug-2024, we observed build-up of white to off-white color powdery materials along with water droplets, wet surfaces, and black to (b) (4) and (b) (4) color material indicative of potential bacterial, fungal and mold growths inside Air Purification Units (APUs) on and after the (b) (4) HEPA filters of the (b) (4) Ducts along with the chamber (b) (4) of randomly selected Module (b) (4) ID: (b) (4)

The (b) (4) and (b) (4) equipment status for Module (b) (4) on 26-Aug-2024 was as follows:

Module	Campaign Product Name	B. No.	Current Campaign Start Date	No. of batch in the campaign	Previous Product Prior to Current campaign / Batch No.	Equipment status on 26-Aug-2024
(b) (4)						

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Medchal-Malkhajgiri District, Telangana, 500043 India	Drug Product Manufacturer

(b) (4)

[redacted]

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(b) (4)

On 26-Aug-2024, we observed build-up of white to off-white color powdery materials along with water droplets, wet surfaces, and black to (b) (4) and (b) (4) color material indicative of potential bacterial, fungal and mold growths inside Air Purification Units (APUs) on and after the (b) (4) HEPA filters of the (b) (4) Ducts along with the chamber (b) (4) of randomly selected Module (b) (4) ID: (b) (4)

The (b) (4) and (b) (4) equipment status for Module (b) (4) on 26-Aug-2024 was as follows:

Module	Campaign Product Name	B. No.	Current Campaign Start Date	No. of batch in the campaign	Previous Product Prior to Current campaign / Batch No.	Equipment status on 26-Aug-2024
(b) (4)						

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The (b) (4) non-dedicated (b) (4) (b) (4) among the total (b) (4) non-dedicated (b) (4) are used in the manufacturing of (b) (4) drug products from Module (b) (4) (b) (4) drug products from Module (b) (4) and (b) (4) drug products from Module (b) (4) of which the following drug products at varying strengths are sold into the USA market:

Module (b) (4) Block)

(b) (4)

Module (b) (4) Block)

(b) (4)

Module (b) (4) Block)

(b) (4)

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Medchal-Malkhajgiri District, Telangana, 500043 India	Drug Product Manufacturer

On 27-Aug-2024, your firm collected multiple swab samples from different locations of the chamber after the (b) (4) (b) (4) (b) (4) ID: GGP/MA/035 and analyzed swab samples for chemical analysis by HPLC and UV Spectroscopy methods to identify the presence of drug substances of the previously manufactured drug products. Test data revealed the presence of different drug substances observed above the acceptance limit indicating a potential risk for drug products cross-contamination with other drug products active materials (drug substances) that were manufactured using the (b) (4) GGP/MA/035. Swab samples test results for chemical analysis by HPLC, and UV-Spectrometry are tabulated as follows:

Table 2

SWAB CHEMICAL ANALYSIS RESULTS (HPLC by UV detector)					
Sr. No.	**Product Name**	**Location details**	**Peak Detected at RT @** (b) (4)	**Results in ppm**	**Acceptance criteria**
(b) (4)					

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Table 3

SWAB CHEMICAL ANALYSIS RESULTS (HPLC by PDA detector)					
Sr. No.	**Product Name**	**Location details**	**Peak Detected at RT @** (b) (4)	**Results in ppm**	**Acceptance criteria**
(b) (4)					

Table 4

SWAB RESULTS GENERATED PER NEW VALIDATION METHOD (GGPROAMV428)					
Sr. No.	**Product Name**	**Location details**	**Peak Detected at RT @** (b) (4)	**Results in ppm**	**Acceptance criteria**
(b) (4)					

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Table 5

		[redacted] (b) (4) Molecule – UV Results	
Sr. No.	**Sample Location**	**Observed QC results (PPM)**	**Acceptance criteria (ppm)**
[redacted] (b) (4)			

		[redacted] Molecule – UV Results	
Sr. No.	**Sample Location**	**Observed QC results (PPM)**	**Acceptance criteria (ppm)**
[redacted] (b) (4)			

		[redacted] Molecule – UV Results	
Sr. No.	**Sample Location**	**Observed QC results (PPM)**	**Acceptance criteria (ppm)**
[redacted] (b) (4)			

Furthermore, swab sample testing of [redacted] (b) (4) (refer to **Tables 2 to 4**) showed unknown peaks, many of which had an area response several times higher than the known active peak, randomly eluting at different retention times in multiple swab samples tested by HPLC. These unknown peaks were not identified and accounted for in the above table. There is a potential that the unknown peaks could be due to active and degradant materials of drug products manufactured using these [redacted] (b) (4) Your firm could not identify all the unknown peaks found in swab samples during the inspection.

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On Aug-27 and 29-2024, swab samples were collected by your firm from the areas of APUs at the (b) (4) (b) (4) of the (b) (4) non-dedicated (b) (4) (b) (4) The testing of swab samples for microbial tests of these equipment revealed several TNTC (Too Numerous To Count) fungal, bacterial, and Total Viable Particulate Count (TVPC) colonies. There is a potential for microorganisms, fungal, yeast and mold grown inside these areas of APUs and (b) (4) to get carried with the high velocity air through the (b) (4) into these (b) (4) and potentially contaminate the product while it is used for the manufacturing of drug products.

Table 6

(b) (4)

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(b) (4)

[redacted]

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(b) (4)

Following the swab sample chemical test results for Module (b) (4) ID: GGP/MA/035), your firm reported Field Alerts for some but not all drug products that are manufactured in module (b) (4) of (b) (4) block. The FARs were reported on 30-Aug-2024 for (b) (4) Tablets USP (b) (4) mg/ (b) (4) mg/ (b) (4) mg (b) (4) Tablets USP (b) (4) mg/ (b) (4) mg (b) (4) mg (b) (4) and (b) (4) mg (b) (4) However, there were no FARs reported for drug products manufactured using Module (b) (4) upon obtaining TNTC results for fungal, bacterial and TVPC. This was in deviation of your SOP No.: GGQA067, Titled: "Handling of Field Alert Reports" for filing field alerts. Additionally, you performed no risk and impact assessment to evaluate quality attributes pertaining to bacterial and fungal contaminations on the batches distributed into the USA market.

B. On 01 and 02-Sep-2024, your firm collected multiple swab samples from different locations at the (b) (4) (b) (4) of the following equipment:

(b) (4)

The swab samples were analyzed per protocol GGP/CVP/MSAT/031-A-24 for chemical analysis by HPLC, and UV Spectroscopy methods to identify the presence of drug substances of the previously manufactured drug products. Test data revealed the presence of different drug substances above acceptance limit indicating a potential risk for drug products cross-contamination with other drug products active materials (drug substances) that were

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manufactured using (b) (4) Swab samples test results for chemical analysis by HPLC and UV Spectroscopy are tabulated as follows.

Table 7

(b) (4)

[redacted]

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Table 8

(b) (4)

[redacted]

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Table 9

(b) (4)

[redacted]

Table 10

(b) (4)

[redacted]

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Table 11

[redacted] (b) (4)

Furthermore, swab samples testing of these [redacted] (b) (4) (refer to **Tables 7, 8, 10 and 11**) showed unknown peaks, many of which had an area response several times higher than the known active peak, randomly eluting at different retention times in multiple swab samples tested by HPLC. These unknown peaks were not identified and accounted for in the above table. There is a potential that the unknown peaks could be due to active and degradant materials of drug products manufactured using these [redacted] (b) (4) Your firm did not attempt to identify all unknown peaks during the inspection. Additionally, your firm reported no Field Alerts for drug products that were manufactured using these [redacted] (b) (4) of your [redacted] (b) (4) block.

C. Your Preventative Maintenance (PM) of [redacted] (b) (4) is deficient for the following reasons:

1. Your firm simply focused on replacing [redacted] (b) (4) HEPA filters of APUs without understanding the purpose of these filters. For example,

Your procedure SOP No.: GGMN212, Titled: "PROCEDURE TO PERFORM HEPA FILTER INTEGRITY TEST AND NON VIABLE PARTICLE COUNT TEST FOR PROCESS EQUIPMENTS", Version: 06, Effective date: 06-Jun-2024 is deficient. There is no mention of Quality Unit responsibilities on the physical verification of the condition of [redacted] (b) (4) Duct, [redacted] (b) (4) HEPA filters and overall conditions of APUs of [redacted] (b) (4) during periodic

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preventative maintenance. As a result, your Quality Unit failed to evaluate conditions of these areas of your APUs of (b) (4) during (b) (4) HEPA filters integrity test and (b) (4) replacement of (b) (4) HEPA filters. In lack of your Quality Unit oversight, your Engineering unit simply focused on following the timelines for the replacement of these filters without understanding the purpose of these (b) (4) HEPA filters was to block particles larger than (b) (4) and that there should not be any powdery materials present inside the (b) (4) Duct and the surrounding areas of (b) (4) HEPA filter inside APU. As a result, there were no investigation logged to determine the impact and risk of potential products cross-contamination.

On 26-Aug-2024, we observed powdery materials and potential dust particles encrusted in areas of (b) (4) Duct, and (b) (4) HEPA filters. Further, white powdery materials were also observed inside the compartment of (b) (4) HEPA filters and (b) (4) filters indicating the integrity of (b) (4) HEPA filters may have been compromised for Module (b) (4) ID: GGP/MA/035. Swab samples collected from these areas on 27-Aug-2024 revealed presence of active compounds of previously manufactured drug substances (refer to **Tables 2 to 5**) and TNTC bacterial and fungal colonies (refer to **Table 6**).

2. Your (b) (4) HEPA filter integrity test and (b) (4) HEPA filter replacement for (b) (4) is deficient as there is no evaluation of the condition of (b) (4) HEPA filter and its assembly for cleanliness.

D. Cleaning of processing equipment is not adequately performed or documented. For example:

1. As part of Type-B cleaning of (b) (4) material adhered from (b) (4) is (b) (4) from the chamber and collected prior to cleaning the (b) (4) bowl. On 26-Aug-2024 during the Type-B cleaning performed for (b) (4) prior to the manufacture of (b) (4) Tablets USP (b) (4) mg (b) (4) we observed significant quantities of material remaining on the walls of (b) (4) after the cleaning checklist indicated this had already been completed. According to procedure GGMF194 and documented within respective batch production records, this material can be later (b) (4) from the (b) (4) into the corresponding batch after visual inspection of the material is conducted.

2. As part of Type-A cleaning of compression equipment (b) (4) the material is to be removed from the (b) (4) surface by (b) (4) the (b) (4) and (b) (4) punches are to be cleaned by (b) (4) On 27-Aug-2024 during the Type-A cleaning of Compression equipment (b) (4) prior to the manufacture of (b) (4)

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	FEI NUMBER 3004097901

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Anil Arora, President - Global Manufacturing Operations

FIRM NAME	STREET ADDRESS
Granules India Limited	Survey No 160/A, 161E, 162 And 174/A, Gagillapur Village, Dundigal-Gandimaisamma Mandal
CITY, STATE, ZIP CODE, COUNTRY Medchal-Malkhajgiri District, Telangana, 500043 India	TYPE ESTABLISHMENT INSPECTED Drug Product Manufacturer

[redacted] mg [redacted] tablets [redacted] we observed apparent visible powder on [redacted] punches, on the [redacted] and within dies from the previous batch manufactured.

Furthermore, upon returning to the compression area on 27-Aug-2024, the compression equipment had been further cleaned by your operations personnel. This additional cleaning conducted was not documented within your executed cleaning record.

QUALITY SYSTEM

OBSERVATION 2

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically, your investigations pertaining to Out of Specification (OOS) and Out of Trend (OOT) investigations are not thoroughly investigated and the CAPA taken is inadequate to determine the risk to the drug products sold into the US market. For example,

A. Your OOS and OOT Investigations for Process Validation (PV) batch # [redacted] 3rd batch of PV) are not thoroughly investigated for Product: [redacted] mg and [redacted] mg Tablets [redacted] For example, the following investigations relating to this PV are found deficient:

1. OOS Investigation number: OOS/049/21, date of initiation: 30-Mar-2021, Issue: OOS result reported for [redacted] test by [redacted] Results [redacted] %, Limit: NLT [redacted] % and NMT [redacted] %, and for [redacted] %RSD [redacted] %, Limit: NMT [redacted] %, Stage: In-process control test, Final classification: Valid OOS
2. OOS Investigation number: OOS/052/21, date of initiation: 05-Apr-2021, Issue: OOS result reported for Assay by [redacted] test: [redacted] %, Limit: NLT [redacted] % and NMT [redacted] %, Stage: [redacted] Tablets at in-process control test, Final classification: Valid OOS

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3. OOT Investigation number: OOT/041/21, date of initiation: 09-Apr-2021, Issue: OOT result reported for [(b) (4)] test with average of [(b) (4)]%, Trend limit: Above [(b) (4)]%, Stage: [(b) (4)] Tablets at in-process control test, Final classification: Valid OOT
4. OOT Investigation number: OOT/018/23, date of initiation: 08-Mar-2023, Issue: OOT result reported for [(b) (4)] test by HPLC for vessel [(b) (4)]% for [(b) (4)] Trend limit: for individual results above [(b) (4)]%, Stage: Long term stability (25°C/60%RH) at 18 month, Final classification: Valid OOT

For the failing batch # [(b) (4)] (3rd batch of PV) at in-process control tests relating to [(b) (4)] by [(b) (4)] and Assay by [(b) (4)] tests, your firm did not reject the batch as you rejected batch # [(b) (4)] (1st PV batch) for the similar test failure. Your batches # [(b) (4)] (1st PV batch post rejection [(b) (4)] and [(b) (4)] 2nd PV batch) also failed the first set of [(b) (4)] samples for [(b) (4)] by [(b) (4)] test for [(b) (4)] content indicating a systemic problem with the manufacturing of [(b) (4)] mg and [(b) (4)] mg Tablets [(b) (4)]

Further, your in-process specification for [(b) (4)] mg and [(b) (4)] mg Tablets [(b) (4)] (Product code: [(b) (4)] Specification No.: [(b) (4)] ersion: 03, Effective date: 20-Feb-2020 is inadequate. Per this specification, [(b) (4)] *test shall be performed for exhibit and validation batches. If* [(b) (4)] *test results do not meet to the specification limits,* [(b) (4)] *shall be released for compression by proposing* [(b) (4)] *sampling at compression stage".* There was no justification provided for this provision to bypass failing test results at [(b) (4)] stage and continuing to use the failing [(b) (4)] batch # [(b) (4)] in the manufacturing. Also, there was no justification provided for how test results of [(b) (4)] tablets [(b) (4)] tablets at post compression) would be representative of the entire batch size of [(b) (4)] tablets). As such, your test results at compression stage for [(b) (4)] tablets failed for Assay by [(b) (4)] est (OOS/052/21 – Valid OOS).

Moreover, your firm dispatched the failing batch # [(b) (4)] (3rd PV batch) along with batches # [(b) (4)] 1st PV batch) and [(b) (4)] (2nd PV batch) into the US market on [(b) (4)] Subsequently, your firm added [(b) (4)] more batches as batches # [(b) (4)] to the same process validation report number: GGP/PVR/TT/MFG/012-A-21, approval dated: [(b) (4)] and concluded the process validation based on the

manufacturing and testing outcome of (b) (4) batches of which batch # (b) (4) (3rd PV batch) confirmed OOS and OOT test results. You manufactured tota (b) (4) batches and dispatched them into the US market between (b) (4) (b) (4) About (b) (4) out of (b) (4) batches distributed in the US market are still within the product shelf life.

Lastly, the evaluation of market complaint revealed lack of efficacy complaint received for batch # (b) (4) PV batch) for which the complaint investigation was limited to only (b) (4) trend evaluation for the similar complaints and not to the entire shelf life of (b) (4)

B. Your OOT Investigation relating to unknown/unspecified impurities are deficient. For example,

1. OOT Investigation number: OOT/069/21, Products: (b) (4) Tablets USP (b) (4) ng and (b) (4) mg, Batch numbers (b) (4)
   Results: (b) (4) %
   Specification: (b) (4) %, Trend limit: NMT (b) (4) % of the specification limit.
2. OOT Investigation number: OOT/071/21, Products: (b) (4) Tablets USP (b) (4) mg, Batch numbers: (b) (4)
   Results: (b) (4) %
   Specification: NMT (b) (4) %, Trend limit: NMT (b) (4) % of the specification limit.
3. OOT Investigation number: OOT/072/21, Products: (b) (4) Tablets USP (b) (4) mg, Batch numbers: (b) (4)
   Results (b) (4) %
   Specification: NMT (b) (4) %, Trend limit: NMT (b) (4) % of the specification limit.
4. OOT Investigation number: OOT/077/21, Products: (b) (4) Tablets USP (b) (4) mg, Batch numbers: (b) (4)
   Results: (b) (4) %
   Specification: NMT (b) (4) %, Trend limit: NMT (b) (4) % of the specification limit.

Your firm concluded the above OOT investigations for batches tested at release based on identifying the unknown peak found in their finished product at about (b) (4) This unknown peak was present in API lots

that were used in manufacturing these batches from one of your API suppliers. This impurity peak was identified as "Related Compound (b)(4), by your API supplier for which your firm established "Control Strategy and Action Plan" mentioning in your investigation that *"Decision taken to not to use **** source API lots in the manufacturing of (b)(4) Tablets USP (Product codes: (b)(4) If needed, **** API lots to be tested against drug product test method # (b)(4) through a proper communication and shall be used if the* ***unknown impurity levels below*** *(b)(4)%"*. However, your firm did not follow this "Control Strategy and Action Plan" and released the batches # (b)(4) listed under each OOT investigations) into the US market.

Further, you (b)(4) only (b)(4) batches (b)(4) out of (b)(4) on long term stability which does not ensure the product performance for the remaining (b)(4) batches (b)(4) (b)(4) throughout the product shelf life until (b)(4) There is a potential that "Related Compound (b)(4) may have increased over the period of shelf life.

C. (This is a repeat observation from the January 2023 inspection)

Your Deviation investigation number: DEV-GGP-23-0224, date initiated: 08-Sep-2023, Issue: OOS value was reported for swab sample analysis for equipment name: (b)(4) Blister Packaging Machine, equipment number: GCW/PP/027, swab location: Product (b)(4) Cleaning Verification for (b)(4) active swab analyses test result: (b)(4) PPM, Acceptance limit: NMT (b)(4) PPM.

Upon observing the failing test result during (b)(4) cleaning verification, your firm did not extend the impact of equipment cleaning practices on the potential risk for cross-contamination to the previous products that were packaged using non-dedicated (b)(4) Blister Packaging Machine. Along with (b)(4) this blister packaging equipment was largely used for (b)(4) drug products packaging.

D. Your OOT Investigation number: OOT/124/22, Products (b)(4) Tablets USP (b)(4) mg (b)(4) mg (b)(4) mg, Batch numbers and stability timepoint: (b)(4) (25°C/60%RH – 24 month), (b)(4) (25°C/60%RH – 36 month), and (b)(4) (25°C/60%RH – 24 month), Test: Organic Impurity by (b)(4) test, Issue: Related Compound Impurity (b)(4) t retention time (RT) about (b)(4) was OOT, Manufactured in Module (b)(4) Block.

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Results: [redacted] (b) (4) %

Limit: NMT [redacted] (b) (4) %

OOT Status: Invalid

Your firm invalidated the OOT results based on assumption of the most probable root cause could be due to glassware contamination without proving through testing that how Related Compound Impurity [redacted] (b) (4) could be present in the glassware to the significant level to reach to the level of OOT.

OBSERVATION 3

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

Specifically,

Your Quality Unit lacks oversight on the control and management of GMP documents that are critical in ensuring drug products manufactured and tested at your site are safe and effective. For example, at the initiation of this inspection on 26-Aug-2024, we observed three (3) trucks full of scrap materials leaving from your facility at around 8:19 am. The inspection of scrap materials from these trucks revealed presence of large number of torn pieces of GMP documents such as analytical balance printouts, worksheets with handwritten documentation in "blue color indelible ball-point ink pen" which were signed and dated along with large number of uncontrolled papers torn into pieces and crumpled having manufacturing and testing information. Similarly, during the walkthrough inspection of your QC laboratory, we observed cleaning personnel removing a large black color scrap bag from the area. The evaluation of this scrap bag revealed a large number of torn and few intact pieces of analytical balance printouts, pH meter printouts, and some printouts similar to Karl Fisher [redacted] (b) (4) test equipment. We also observed many torn pieces of uncontrolled white papers with GMP information documented in blue indelible ball-point ink pen pertaining to testing activities. Per your SOP No.: GIL-CQA-028, Titled: "Good Documentation Practices", Version: 03, Section: 5.37 "blue indelible ball-point ink pen" is used for recording of GMP documentation.

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We also observed handwritten documentation in "green color indelible ball-point ink pen" on large number of uncontrolled papers torn into pieces and crumpled having manufacturing and testing information. Per your SOP No.: GGQA 057, Titled: "Responsibilities of Quality Assurance", Version: 04, Section: 5.3.4 "The QA personnel shall use the green color indelible ball-point pen at applicable areas of work i.e. manual issuance of documents, IPQA related activities involved logbooks, formats, labels, BPR entries, approval of COA, certificate of compliance, release and approval of executed batch records/analytical records".

There is also a lack of Quality Unit oversight on employee practices of documenting GMP data on uncontrolled white paper and later disposing of these papers by tearing into pieces inside scrap bags. Among multiple sections violated by destroying GMP documents, section 5.1.4 of SOP No.: GIL-CQA-012, Titled: "Data Integrity", Effective date: 30-Aug-2022 refers to ALCOA+ principle to ensure integrity of data and Good Documentation Practices.

Upon putting together some of the torn pieces of documents with the help of your employees, your Quality Unit management stated the torn pieces belonged to original record, raw data and metadata pertaining to QC and manufacturing units and these documents should not have been destroyed. For example, but not limited:

1. Material Name: (b) (4) Tablets (b) (4) mg (b) (4)
   Batch Number: (b) (4) A.R. Number: (b) (4) Specification Number (b) (4) STP Number: (b) (4)

   The completed and signed off Raw Data Worksheets pertaining to Description, Identification of (b) (4) by (b) (4) tests were torn into pieces by the Analyst. These torn Raw Data Worksheets were collected from one of the scrap material trucks at the initiation of inspection on 26-Sep-2024.

2. Product Name: (b) (4) Batch Number: (b) (4) A.R. Number: (b) (4) Specification Number: (b) (4) STP Number: (b) (4) Worksheet Number (Raw Data Sheet): GGRDSMSC001.

Analytical weight printouts (2) for Sartorius Balance ID: QC-284 were torn into pieces by the Analyst. The evaluation of some of the torn pieces revealed the weighing activities pertaining to (b) (4) Analysis tests. The weights on the torn printouts and those found affixed inside your worksheets depicted different weights on the torn balance printouts. These torn balance printouts were collected from a scrap bag from QC laboratory that your cleaning personnel tried to remove from the QC laboratory during the walkthrough inspection on 26-Sep-2024.

PRODUCTION SYSTEM

OBSERVATION 4

A. The process of (b) (4) material from the (b) (4) commonly performed during routine manufacturing, including (b) (4) used in (b) (4) containing drug products for the US market, has not been adequately assessed to ensure that material obtained from this process is of suitable quality prior to further processing. For example:

1. The material adhered to the walls of the (b) (4) chamber and within the (b) (4) are allowed to be collected through (b) (4) as applicable, and inspected for physical appearance, as outlined in procedure GGMF194, "Inspection of (b) (4) material from (b) (4) and in associated cleaning records. There has been no documented scientific evidence that the material (b) (4) and collected meets the minimum in-process check of other (b) (4) material prior to (b) (4) including during evaluation of samples from the most recent process validation of (b) (4) completed in December 2023 or during routine production. In addition, there has been no evaluation of other quality attributes, including related substances, that could negatively impact the quality of the (b) (4) material that has adhered to the chamber walls during the successive lot processing and prior to use in further (b) (4) unit operations.

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2. After the [(b) (4)] of the material has occurred, a significant amount of material may remain adhered to the walls within the chamber of the [(b) (4)] as observed on 26-Aug-2024 during Type-B cleaning of the [(b) (4)] This material may be then carried over into the next campaign batch, where the [(b) (4)] and material is subjected to further [(b) (4)] operations. The equipment is not Type-C cleaned until there is a product change over or the defined campaign length has been reached. There has been no scientific evaluation during the campaign length determination studies of the quality impact this carryover material has on subsequent campaign batches.

B. The documentation of [(b) (4)] material into the batch is deficient including during the manufacture of [(b) (4)] Tablets USP [(b) (4)] mg [(b) (4)] Batch [(b) (4)] for the following:

1. The [(b) (4)] process is documented as part of the cleaning record of the equipment and requires that the [(b) (4)] s [(b) (4)] and the [(b) (4)] is removed prior to [(b) (4)] There is no documented evaluation of the surrounding area prior to opening to ensure no cross-contamination with other operations in the area, including other cleaning or manufacturing operations.

2. Once visual examination is completed, the [(b) (4)] material is [(b) (4)] the batch. However, there is no record of who performed and verified the [redacted] and when, how, and at what unit operation the collected material was [(b) (4)] the batch.

Furthermore, market complaint MC-GGP-23-0066 was received on 03-Mar-2023 due to the presence of black particles in [(b) (4)] Batches [(b) (4)] The root cause of the complaint was determined to be the active ingredient, [(b) (4)] which was adhered to the wall of the [(b) (4)] [(b) (4)] turning [(b) (4)] in color and the inspection of the [(b) (4)] material missed observing the particle as described in procedure GGMF194. The investigation is inadequate as it did not extend corrective actions to other product [(b) (4)] where [(b) (4)] and the [(b) (4)] process is used, it did not evaluate or identify those products in which quality attributes may be impacted by the [(b) (4)] and the [(b) (4)] process, and it did not evaluate the adequacy of the visual inspection process and propose corrective actions related to this attributable root cause.

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OBSERVATION 5

Written procedures are not followed that describe the in-process controls to be conducted on appropriate samples of in-process materials of each batch.

Specifically,

A. During the in-process sampling and testing for [redacted] Tablets USP [redacted] mg Batch [redacted] the following discrepancies were observed for the sample collected on 27Aug2024 at 10:54 AM:

1. According to the batch production record, the operator is to inspect both faces of [redacted] tablets from the [redacted] of the compression equipment for tablet description verification. We observed and your operator verbally confirmed that they did not count the tablets nor did they look at both sides before documenting the tablet verification results and transferring to the [redacted] in-process sample container.

2. The operator is to perform a weight check of [redacted] tablets from [redacted] the compression equipment. We observed and your operator verbally confirmed that the weight check utilized [redacted] tablets collected and stored within the [redacted] in-process sample container, and the samples were not discreetly tested from [redacted] the compression equipment.

B. During the in-process testing for [redacted] Tablets USP [redacted] mg Batch [redacted] on 27-Aug-2024, we observed one tablet obtained a [redacted] reading of [redacted] which did not pass the in-process limit of [redacted] of [redacted] According to procedure GFMF009, "In-process Checks and Log Book Entries During Manufacturing Stages", a deviation is to be opened in the event of a parameter found out of the specified limit given. However, a note was added to the printout and the sample was reanalyzed with no investigation with no investigation conducted.

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FACILITY AND EQUIPMENT SYSTEM

OBSERVATION 6

Building and facilities are not maintained to ensure that products manufactured meet the quality, purity characteristics, identity and strength which they purport.

Specifically,

A. On 26-Aug-2024, we observed (b) (4) filters of your randomly selected Air Purification Units pertaining to Module (b) (4) ID: (b) (4) and Module (b) (4) ID (b) (4) were severely damaged and torn in many sections indicating these filters may have lacked integrity to block particles larger than (b) (4) As a result, we observed the (b) (4) HEPA filters contained apparent dust, powdery materials, and wet surfaces. Further, we observed patches of white powdery materials extruding from the corners of (b) (4) HEPA filters indicating the integrity of these filters may have been compromised.

During the inspection, per our requests your firm collected and tested swab samples from the (b) (4) (b) (4) HEPA filters of Module (b) (4) ID: GGP/MA/035. The swab analyses test results revealed presence of drug substances of previously manufactured drug products (refer to **Tables 2 to 5 and 9**) and colonies of bacterial and yeast (refer to **Table 6**).

B. During the walkthrough inspection of your service floor on 26-Aug-2024, we observed your Air Purification Units (APUs), Air Handling Units (AHUs), (b) (4) water tank, Equipment Cleaning Skid, (b) (4) Ducts, (b) (4) Ducts, along with the floors and surfaces of equipment and utilities were covered with apparent off-white to white powdery materials and dust. Additionally, we observed the following concerns relating to the condition of your facility and equipment:

1. Bird droppings and feathers on the APUs, (b) (4) Ducts, (b) (4) water tank, cleaning skid, and the floors surrounding to Module (b) (4) D (b) (4) The walls surrounding equipment were not secured enough in sections to prevent birds from getting inside the facility and stop dust and other environmental elements from damaging your equipment and facility.
2. The (b) (4) water tank had apparent reddish brown color stains indicating the tank was apparently rusted in the sections that contained water. The (b) (4) water tank and areas surrounding had wet surfaces and pool of standing water indicating potential for microbial, yeast and mold growth in these areas. Per General

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Manager of Engineering, the tank has never been cleaned since its installation several years back. Per your Quality and Engineering General Managers, this water termed as [(b) (4)] water" is used in cleaning [(b) (4)] [(b) (4)] sections of [(b) (4)] Ducts of Module [(b) (4)]

3. The high-pressure equipment cleaning skid for Module [(b) (4)] were found inside the pool of standing water. The sections of this cleaning skid and water in which it was placed appeared to have potential growth of microbial, yeast and mold on many sections along with hose that is used for cleaning.
4. The equipment, [(b) (4)] and many sections of equipment were wet, leaking, and as a result corroded in multiple areas.

***DATES OF INSPECTION**

08/26/2024(Mon), 08/27/2024(Tue), 08/28/2024(Wed), 08/29/2024(Thu), 08/30/2024(Fri), 09/02/2024(Mon), 09/03/2024 (Tue), 09/04/2024(Wed), 09/05/2024(Thu), 09/06/2024(Fri)

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