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	2/13/2023-3/2/2023* FEI NUMBER 3001236066

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Amit A. Nigalaye, President

FIRM NAME	STREET ADDRESS
Granulation Technology, Inc.	12 Industrial Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fairfield, NJ 07004-3018	Contract 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:
QUALITY SYSTEM

OBSERVATION 1

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,

A. An out of specification result of 250 cfu/mL for Total Aerobic Plate Count (action limit specification (b) (4)) was observed from the (b) (4) Water System on 06/29/2021, lot 210629 under Investigation Report #21-008 dated, 07/06/2021. *Burkholderia cepecia* and *Pseudomonas chengduensis* were identified as the recovered organisms from the water sample on 07/13/2021. Your firm did not provide a scientific justification to support your purported root causes as (1) the potential contamination during (b) (4) (b) (4) water tank change by an authorized water system technician, (2) (b) (4) water circulates through the water circulation pump for (b) (4) . If water is not utilized possibility of pathogens growing stagnant water increases and (3) sampling error by the QA personnel or sampling handling error by the contract testing laboratory. There has been no assessment performed to evaluate the impact of the recovery of these microorganisms in the following drug products:

1.

SR No	Products	GTI Granulation Lot	Client Lot
1	(b) (4)	Lot: (b) (4) No expiry	Lot: (b) (4)
2	(b) (4)	Lot: (b) (4) No expiry	Lot: (b) (4)

AMENDMENT 2

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	Jessica S Estriplet, Investigator Tanya R Syffrard, Investigator Simone E Pitts, National Expert X Jessica S Estriplet Investigator Signed By: Jessica S. Estriplet -S Date Signed: 03-02-2023 20:58:14	3/2/2023

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	(b) (4)		
3	(b) (4)	Lot: (b) (4) No expiry	Lot: (b) (4)

2.

SR No	Product	GTI Granulation Lot	Client Lot
1	Bismuth (b) (4)	(b) (4) Exp: 02/2025	(b) (4)
2	Bismuth (b) (4)	(b) (4) Exp:02/2025	(b) (4)

B. Your Quality Control Unit (QCU) failed to evaluate the impact of microorganisms recovered from the (b) (4) Water system and Finished Products during the period of 2020 to 2021. Results ranged from 120 - 430 cfu/mL compared to the specification limit of (b) (4) The investigation reports failed to confirm a root cause of the out of specification result and identification of the microorganisms recovered. The water generated from the (b) (4) Water system is a major component in the manufacturing of (b) (4) , Bismuth (b) (4) . Moreover, no corrective actions have been taken to ensure the water used in manufacturing consistently met the minimum quality standard requirements per USP.

Date	Sample	Lot	Microbial Analysis: Aerobic Plate Count:	Result (cfu/ml)	Microorganism ID
09/21/2020	Water System Use Valve	200921	(b) (4)	4.3×10^2	No Identification
10/12/2020	(b) (4) (b) (4) (b) (4)	(b) (4) No expiry	(b) (4)	1.4×10^2	No Identification
07/07/2021	Water System	210707	(b) (4)	$>2.5 \times 10^2$	No Identification

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	Use Valve		CFU/mL		
11/02/2021	Water System Use Valve	211102	(b) (4)	1.2×10^2	No Identification
11/03/2021	(b) (4) Water (b) (4) (b) (4)	(b) (4)	(b) (4)	1.9×10^2	No Identification

C. No alert limits have been established for the (b) (4) Water system to aid as an indication of a potential quality shift occurring. Per SOP No: 305, *Operation and Maintenance of the* (b) (4) *System*, effective 10/20/2021, revision 04 lists an action limit of (b) (4) for microbial test results. No investigations have been initiated for out of trend results recovered from 2020 - 2022 ranging from 64 - 93cfu/ml. Moreover, no corrective and preventative action plan has been established to minimize and decrease the likelihood of reoccurrence when out of trend results are recovered.

Date	Sample	Lot (Bulk)	Results (cfu/ml)
10/12/2020	(b) (4)		75
10/12/2020			90
10/12/2020			90
10/12/2020			85
10/26/2020	Water System Use Valve	201026	64
11/02/2020	Water System Use Valve	201102	87
01/26/2021	Water System Use Valve	210126	87
02/09/2021	Water System Use	210209	84

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	Valve		
02/23/2021	Water System Use Valve	210223	74
10/26/2021	(b) (4) Water USP (b) (4)	(b) (4)	93
11/09/2021	Water System Use Valve	211109	76
07/12/2022	Water System Use Valve	220712	67

This is an observational repeat from the previous inspection in November 2017.

OBSERVATION 2

The quality control unit lacks responsibility to approve all procedures or specifications impacting on the identity, strength, quality and purity of drug products.

Specifically,

Your Quality Control Unit failed to establish and follow a control system for implementing changes that can potentially affect the identity, strength, purity and quality of drug and OTC products manufactured including but not limited to, Estradiol Tablets, USP 0.5mg, 1mg, 2mg, (b) (4), Bismuth (b) (4). For example,

A. A change control form has not been initiated to assess the removal of a dead leg and the removal and installation of a new (b) (4) (b) (4) for the (b) (4) Water System (May 2021). This change was not initiated nor has been adequately evaluated and approved by the QCU.

B. The (b) (4) Capsule Banding Machine #580 Room 213, installed in September 2022, was not governed by a change control form. The firm failed to ensure the use of the capsule banding equipment

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has any potential effect on product quality.

C. The following equipment was installed on the Packaging and Labeling Line in Room D7 The (b) (4) Tablet Counter #544, installed in July 2020 and (b) (4) Bottle Serilization system installed January 2019 used for tablet counting without the initiation, assessment, review and approval.

OBSERVATION 3

Complaint records are deficient in that they do not include the findings of the investigation and follow-up.

Specifically,

A. Investigation Report #20-012 (ADE# 2020EPC00156, dated 04/23/2020) initiated for a complaint regarding Estradiol Tablets, USP stating the product did not work is inadequate in that your firm failed to include the lot number of the manufacturing record reviewed, the analytical test data reviewed, and the lot number of the stability batch reviewed to support the conclusion there were no quality issues identified that could have attributed to the adverse event. The complaint investigation was reviewed and approved by the Quality Control Unit on 6/5/2020.

B. Investigation Report #21-009 (ADE# A21EP0434/MI384/ADE80, dated 07/23/2021) initiated for a complaint regarding Estradiol Tablets, USP 1 mg reporting an adverse event is inadequate in that your firm failed to include the lot number of the manufacturing record reviewed, the analytical test data reviewed, and the lot number of the stability batch reviewed to support the conclusion there were no quality issues identified that could have attributed to the adverse event. The complaint investigation was reviewed and approved by the Quality Control Unit on 08/23/21.

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C. Investigation Report #20-006 (Case Report: 1-60025759, dated 02/04/2020) initiated for a complaint regarding Estradiol Tablet, USP 1mg, Lot #19076A, reporting the overcount of a bottle that had a tablet count of 200 instead of 100 tablets. The report stated, "An operator's failure to discard the bottle after restarting the tablet counter, and inadvertently placing it back on the filling and packaging line, is believed to be the source of the additional 100 tablets filled in the bottle under investigation". The retain samples of Batch #19076A and (b) (4) additional Estradiol batches were inspected; no discrepancies were noted. The investigation failed to include the lot numbers of the additional (b) (4) batches inspected; a definitive root cause was not identified. The complaint investigation was reviewed and approved by quality assurance on 02/20/2020.

PRODUCTION SYSTEM

OBSERVATION 4

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,

Your firm failed to adequately validate your manufacturing process for your drug products which would provide assurance that your process is capable of consistently delivering a quality product that meets pre-determined specifications.

A. Process Validation for (b) (4) is inadequate. The firm has not addressed the deficiencies observed during the last inspection in November 2017 in reference to the capsule banding process, the metal detection process, and re-processing and re-use of final blend waste powder obtained after capsule filling machine operations.

B. The Performance Qualification for (b) (4) Tablet/Capsule, ID #544 (Date of Issue: 08/19/2020) used for

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the tablet counting steps for Estradiol Tablet, USP 0.5mg, 1 mg, and 2mg is inadequate in that the qualification does not include the name of the product, dosage strength, nor does it include challenges for the multiple bottle count (100 and 500 tablet count) and multiple container sizes (100cc, 120cc, and 300cc). The qualification protocol has not determined if the process is reproducible and can consistently meets the requirements of filling bottles ranging in sizes of 100cc to 300cc with tablets counts of 100 and 500 as documented in the executed batch manufacturing records for Estradiol Tablets, USP. In addition, the Estradiol Packaging Line has not been fully qualified.

C. Your firm failed to validate the (b) (4) Water System to ensure it is designed to demonstrate that you can effectively control, maintain, sanitize, and monitor the system so it consistently produces (b) (4) water that meets the USP monograph and appropriate microbial control limits. This (b) (4) system is circulated through a (b) (4) pump and investigation reports have recovered microbial results that have not been investigated thoroughly.

This is an observational repeat from the previous inspection in November 2017.

FACILITIES & EQUIPMENT SYSTEM

OBSERVATION 5

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

Specifically,

The equipment used to support drug product manufacturing are not maintained to ensure equipment is free of contamination. In Room #101, the (b) (4) Blender #231 is used for the blending of Bismuth (b) (4) During our walkthrough on 02/13/2023, the (b) (4) Blender #231 was identified as clean, however, we observed a white and discolored powder throughout the blender. Bismuth (b) (4)

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(b) (4) is an OTC drug product. The last product manufactured in the (b) (4) equipment was Bismuth (b) (4) (Lot #(b) (4) between the dates of 01/25/2023 and 01/26/2023. The (b) (4) Blender #231 was last cleaned on 01/31/2023 according to the Equipment Usage and Cleaning Log Book No: 02.

On 02/13/2023, during the walkthrough of the facility, the (b) (4) Capsule Filling Machine (Equipment #215) in Room #204, that is used to encapsulate (b) (4) was documented as clean on 02/13/2023 in the Equipment Usage and Cleaning Log (Book NO:03). We observed residual white powder on the site glass of the (b) (4) capsule turret, outside the encapsulation machine on multiple surface areas including, but not limited to, hoses, on ceiling pipping, pails, and drums. (b) (4) were observed within the encapsulation (b) (4) even though the equipment was designated as cleaned. In addition, what appears to be clear tape, was found on multiple surfaces within the encapsulation machine. According to the logbook, the equipment was both cleaned and checked by a second operator on 02/13/2023. The last product that was manufactured on the aforementioned equipment was (b) (4) between the dates of 02/08/2023 and 02/10/2023.

OBSERVATION 6

The building lacks adequate space for the orderly placement of equipment and materials to prevent mix-ups between drug product containers and drug products and to prevent contamination.

Specifically,

During our walk-through of Warehouse (b) (4) on February 13, 2023, we observed staging areas of Quality Control released products, excipients, and Research & Development products co-mingled and stored within close proximity of the quarantine area in the warehouse with no defined areas of demarcation or signage. The firm uses a paper-based system (non-electronic) such as (b) (4) to track the movement of their raw material inventory. For example,

A. (b) (4) QC released fiberboard drums of (b) (4), Raw Material# (b) (4) stored on wooden pallets adjacent to quarantine materials.

B. (b) (4) RM# (b) (4) used for R&D with a (b) (4) quarantine label attached

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stored adjacent to (b) (4) containers of excipients (e.g.: (b) (4) Mfg. Lot No: (b) (4) , date received: 04/01/2022; (b) (4) Lot No: (b) (4) , date received 08/28/2020; (b) (4) , Mfg. Lot No: (b) (4) date received 04/26/2021, and (b) (4) Lot No: (b) (4) date received 03/05/2021 stored on (b) (4) crates).

C. Multiple pallets of (b) (4) Mfg. Lot: (b) (4) date received 10/26/2022 with various inventory designated (e.g.: quarantine and released status).

OBSERVATION 7

Routine calibration and checking of equipment is not performed according to a written program designed to assure proper performance.

Specifically,

On February 14, 2023, during a walk-through of the facility in the Estradiol suite compression area for tablets, we observed the weigh scale #412 used for tablet weights of Estradiol Tablets USP 2mg, Lot #23022 was fluctuating and displaying various numerical values. The scale is located on a stainless-steel table directly under an air flow vent from a HEPA filtration unit and is used for in-process and finished product weight checks. While observing the operator, the displayed value continued to fluctuate and the operator tared the balance, placed the tablet, and tared again, repeating the steps until all tablets were weighed. The balance as present was not leveled (the air bubble indicating correct leveling was out of range of the circle). The vice-president/ consultant of the firm adjusted the corrected leveling, and indicated the balance is okay now. Furthermore, as per SOP No. 508 Scale(s), Operation / Calibration / Cleaning, effective date 11/20/2012 revision 1 procedure section step #2 states, "Check whether the scale/balance is leveled. If it is not leveled,(b) (4) until the leveling bubble is centered in the scale". An assessment has not been performed to evaluate if the balance is accurately weighing tablets as part of in-process testing.

PACKAGING & LABELING SYSTEM

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OBSERVATION 8

Strict control is not exercised over labeling issued for use in drug product labeling operations.

Specifically,

A. Product labels coded with the lot number and expiration date are not reconciled as part of the batch manufacturing record after the completion of packaging and labeling operations. Labels that have been designated as rejected (e.g., incorrect and ineligible lot number and expiration date, incorrect label alignment and adhesion, label damage) are defaced with a black marker and discarded into the garbage. These discarded labels are not accurately reconciled and documented in the batch manufacturing record. Labeling operators were inconsistently utilizing a plain white sheet of paper to attach the labels in order to keep track of the discarded labels. None of the above-mentioned practices were stated in SOP 700 Line REV:03 Line Clearance and in-Process checks for Packaging Operations or any other procedures referencing the packaging and labeling operations.

B. Upon receipt of product labels for Estradiol Tablets, USP 2mg lot #55415, 100 tablet count, as discussed with packaging operator and production supervisor, the operator reviews the incoming labels and selects a label from each roll for inspection. On September 07th 2022, (b) (4) rolls of labels totaling (b) (4) were received, the requirement is to inspect (b) (4) labels per roll for a total of (b) (4) labels; uncontrolled document detailed the accountability of (b) out of (b) (4) labels, the remaining (b) (4) labels were unaccounted for in the documentation. There is no SOP that governs the above practices. An investigation was not initiated to account for the missing labels, the labels were released for use on 9/07/22.

C. Product labels, without printed expiration dates and lot numbers, for Estradiol Tablets 2mg USP lot #23007A were left on the packaging line at the end of day shutdown. On 02/13/2023 and 02/21/2023, we observed a roll of product labels left on the spool at the labeling station on the dedicated Estradiol Packaging Line in Room D7. Operators had shut down packaging operations for the day and exited the room. The room remained unlocked, allowing access by anyone, until packaging operations began the

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next morning. According to SOP #727, Issuance and Reconciliation of Printed Components, Rev 00, effective on 12/20/2018, under procedure section 2.0, states "When the packaging is completed the supervisor will return the remaining unused printed components along with the components that are to be destroyed to the storage area and QA personnel will complete the Packaging Component Reconciliation page in the packaging master record". This required step is not followed as stated in the SOP.

***DATES OF INSPECTION**

2/13/2023(Mon), 2/14/2023(Tue), 2/15/2023(Wed), 2/16/2023(Thu), 2/17/2023(Fri), 2/21/2023(Tue), 2/22/2023(Wed), 2/23/2023(Thu), 2/24/2023(Fri), 3/02/2023(Thu)

X Tanya R Syffrard
Investigator
Signed By: Tanya R. Syffrard -S
Date Signed: 03-02-2023 20:58:55

X Simone E Pitts
National Expert
Signed By: Simone E. Pitts -S
Date Signed: 03-02-2023 20:59:40

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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."