DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
11155 Dolfield Boulevard, Suite 117 Owings Mills, MD 21117 (410)779-5455 Fax:(410)779-5707	3/30/2026-4/3/2026
	FEI NUMBER 3011585184

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Rajesh Kapoor, Global Head - Quality

FIRM NAME	STREET ADDRESS
Granules Pharmaceuticals Inc.	3701 Concorde Pkwy
CITY, STATE, ZIP CODE, COUNTRY Chantilly, VA 20151-1126	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:

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, your firm failed to adequately investigate recurring stability failures for (b) (4) (b) (4) Capsules (b) (4) under (b) (4) stability conditions and did not fully characterize the unknown impurity causing the failures.

For example, (b) (4) Capsules (b) (4) lot (b) (4) had stability failures under (b) (4) conditions (b) (4)) between April 2025 and July 2025. At (b) (4)) (b) (4) conditions, this lot exhibited assay degradation to 89.8% (below the (b) (4) specification), as documented in Incident Report (IR): IR-25-042. At (b) (4)) accelerated conditions, this lot exhibited assay degradation to 88.7% (below the (b) (4) specification), as documented in Incident Report (IR): IR-25-077 and this lot was found to be OOS for unknown impurity (RRT 0.5 minutes), and total impurity limit (NMT (b) (4), as documented in IR-25-080. Additionally, (b) (4) Capsules (b) (4) lot (b) (4) exhibited an assay OOS failure (88.2%) at the (b) (4) (IR-25-077) and an unknown impurity and total impurity OOS at the (b) (4) timepoint (IR-25-080).

Your firm's investigations remain incomplete as the unknown impurity has not been fully characterized, or toxicologically qualified.

OBSERVATION 2

The written stability testing program is not followed.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	David A Oluwo, Investigator Ofuje D Daniyan, Investigator	X David A Oluwo Investigator Signed By: 2001987776 Date Signed: 04-03-2026 13:39:07	4/3/2026

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Specifically, your firm fails to follow SOP GL-059, *Stability Program*, effective date 10/23/2025, in that stability samples are not consistently tested within their respective testing windows.

For example,

a) Your firm failed to pull stability samples for (b) (4) and (b) (4) Tablets, USP (b) (4), Lots (b) (4), and (b) (4) for analytical analysis at the (b) (4) timepoint under (b) (4) storage conditions (b) (4) as documented in IR-25-070. The samples were due to be pulled for analysis on 05/28/2025 but were not pulled for analysis until 07/03/2025, exceeding the allowed testing window.

b) Your firm failed to follow SOP GL-059, *Stability Program*, and perform stability testing (dissolution) for (b) (4) Capsules (b) (4) lot (b) (4) at the (b) (4) timepoint under controlled room temperature (CRT) storage conditions (b) (4)), within (b) (4) from the date of sample withdrawal, as documented in IR-25-071. The sample was pulled on 05/06/2025, and testing should have been completed by 06/20/2025; however, dissolution testing was not completed until 07/03/2025.

c) Your firm failed to follow SOP GL-059, *Stability Program*, and perform stability testing (description, assay, and dissolution) for (b) (4) Tablets USP, (b) (4)) lot (b) (4) at the (b) (4) timepoint under accelerated storage conditions (b) (4)), within (b) (4) from the date of sample withdrawal, as documented in IR-25-091. The sample was pulled on 07/17/2025, and testing should have been completed by 08/16/2025; however, testing was not planned and executed until 08/19/2025.

OBSERVATION 3

Batch production and control records do not include complete information relating to the production and control of each batch.

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Specifically, your firm fails to maintain manufacturing documentation, including complete batch manufacturing record pages and pre-start-up checklists as specified in SOP GP-011, *Preparation and Control of Master Batch Records*, effective date 01/28/2026.

For example,

a) Per IR-25-010 (initiated 02/04/2025), pages 38 – 41 of the batch manufacturing record, for (b) (4) Capsules lot (b) (4), were missing from the batch record that was issued after the dispensing activity. The missing pages could not be located and were re-issued by QA.

b) Per IR-24-047 (initiated 06/13/2024), the entire batch manufacturing record for (b) (4) Tablets lot (b) (4), was missing after issuance on the day of dispensing, (b) (4), and was not found until (b) (4) The batch record was subsequently returned to document control, and a new replacement batch record (b) (4) was issued for dispensing.

c) Per IR-25-055 (initiated 05/29/2025), the Pre-Start-Up Checklist was missing from the batch record bundle for (b) (4) Capsules, USP (b) (4) lot (b) (4) as identified during batch record review. The checklist could not be located by your firm. Additionally, per IR-24-144 (initiated 12/30/2024): the Pre-Start-Up Checklist for the (b) (4) stage was missing from the batch record bundle for (b) (4) Capsules - (b) (4) for (b) (4) and (b) (4) lot (b) (4) The checklist could not be located by your firm.

OBSERVATION 4
Buildings used in the holding of a drug product are not maintained in a good state of repair.

Specifically, your firm failed to adequately maintain critical HVAC equipment supporting GMP storage areas.

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For example,

On 12/31/2025 (IR-25-129), and again on 02/01/2026 (DEV-00059), Air Handling Unit (b) (4) (AHUF (b) (4) serving Building 3701 Warehouse Dock (b) (4) experienced (b)(b) (4) pipe failures resulting in water leakage onto stored pharmaceutical materials, resulting in rejection of impacted materials, such as (b) (4) USP lot (b) (4) under IR-25-129 and (b) (4) lot (b) (4) under DEV-00059. Per IR-25-129, the root cause was the (b) (4) failed due to faulty controls. The control system did not shut the outside air damper and did not open the (b) (4) valve when the freeze stat was triggered due low outside temperature. Additionally, the freeze stat was not wired properly to the (b) (4) t valve or the outside air damper.

The Investigations (IR-25-129 and DEV-00059) determined the root cause was the (b) (4) failed due to faulty controls and improper wiring of the freeze stat to the (b) (4) valve or outside air damper, which prevented the outside air damper from closing and the (b) (4) valve from opening during low outside temperatures/freezing conditions. The investigations noted that preventive maintenance had been performed (b) (4) as scheduled, yet preventive maintenance failed to detect the improper wiring.

X Ofuje D Daniyan
Investigator
Signed By: 2004083158
Date Signed: 04-03-2026 13:40:03

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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."