DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Food and Drug Administration/CDER/OPQ/OS White Oak, Building 51, Room 4316 10903 New Hampshire Avenue, Silver Spring, MD 20993 Attn: Mr. Concepcion (Coki) Cruz Phone: 001-301-796-3254 Fax: 001-301-847-8738	December 5-9, 2016
	FEI NUMBER 3012806860

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Mr. Kakarlapudi Venkata Viswanatha Raju, Chief Executive Officer

FIRM NAME	STREET ADDRESS
Granules Omnichem Private Limited	Pharmacity SE Parawada (Mandal), Plot 121 (Part) & 122 Jawaharlal Nehru
CITY, STATE, ZIP CODE, COUNTRY Visakhapatnam, Andhra Pradesh, India	TYPE ESTABLISHMENT INSPECTED API 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 I/WE OBSERVED:

QUALITY SYSTEM

OBSERVATION 1

The Quality Unit cannot ensure the review of all deviation reported during production prior to finial product batch release.

Specifically,

Your Remarks Forms # GP-0004-D07 and # GP-0004-D078, ver 2, effective 12-15-2014 used to report production deviations are provided on an as needed basis by the Production department directly to the production operators.

Traceability of these forms relies on the production operator to write in the form number and ensure all pages are include in the batch record. There are 21 cases where the production operator omitted or repeated numbering the forms. There is no assurance all Remarks Forms are included in the batch record and are reviewed by the Quality Unit prior to batch release.

In addition, the Production department determines the need for further investigation based on the deviation reported in the Remarks Form. Therefore the Quality Unit cannot ensure appropriate actions are not taken for each deviation reported in the Remark Form.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE H.L. Jamillah Selby, Investigator Doan T. Nguyen, Investigator	DATE ISSUED 12/9/2016

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OBSERVATION 2

Employee was not trained prior to conducting the cleaning of the Microbiology Laboratory ISO Class 8 room.

Specifically,

On 12/06/2016, I observed, the cleaning log book for the Microbiology Laboratory ISO Class 8 room was cleaned three times by (b) (6) who was not trained on the SOPs titled "Cleaning Procedure for Microbiology" and "Entry and Exit Procedure for Microbiology" until 5 days after first cleaning.

OBSERVATION 3

Change Control system does not evaluate and reflect all changes that may affect the production of the finished product.

Specifically,

I. Process Change Control PCR-MFI (b) (4) 006 for (b) (4) Batch (b) (4) did not include

   a. An adequate justification and evaluation of the addition of a (b) (4) There is no technical justification for the addition of the (b) (4) process, evaluation of the impact to the product, or specifications for the equipment to be used.

   b. Changes observed between (b) (4) batch record (b) (4) B01-V03 and (b) (4) B01-V04 were not completely documented and evaluated for the following: identification of Critical Parameters, the additional, removal or change of manufacturing instructions, (b) (4) speed, and recording (b) (4) ntervals.

OBSERVATION 4

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Production Master Batch Records are incomplete.

Specifically,

Your Master Batch Record for the production of (b) (4) and (b) (4) does not include the issuance of Remarks Form # GP-0004-D07 and # GP-0004-D08 ver 2, effective 12-15-2014 used to capture the following: devi tions, documenting additional oper tions, comments, observations, and addition l s mpling

Some examples, but not limited to 21 omitted numbers used to identify Remarks Form for batch # (b) (4) and # (b) (4) missing supervisor signatures and duplicate form numbers. Some examples of comments in these Remarks form include time period change for batch to reach required (b) (4) sampling request, and change in production directions.

LABORATORY SYSTEM

OBSERVATION 5

Laboratory control records do not include complete data derived from all tests conducted to ensure compliance with established specifications and standards, including examinations and assays.

Specifically,

An lytical records for the analysis of (b) (4) (b) (4) Related Substances by HPLC for Batches (b) (4) (b) (4) and (b) (4) we observed your records do not include documentation of the preparation of sample soluti , stability solutions and reagents. In addition the quantity of the solution prepared, the d te of preparation and the expiation date of the solution are also not documented.

FACILITIES AND EQUIPMENT

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OBSERVATION 6

The Facility design and maintenance increases the potential for contamination of your equipment and product.

Specifically,

On, 12/5/2016, during the walk though of the production area we observed the following:

- The room used to store clean equipment contains a gap in the ceiling which spans across the length of the room that is approximately (b) (4) inches wide exposing the (b) (4) material of the adjacent room and extents up to the roof.
- Cracks in the walls and peeling and chipping paint along the wall and light fixtures.
- The appearance of water damage to the drywall in various locations.

MATERIAL SYSTEM

OBSERVATION 7

Materials should be handled and stored in a manner to prevent degradation, contamination, and cross-contamination.

Specifically,

Raw material (b) (4) approved by QA on 8/10/2016 was observed being stored in the raw material warehouse which is maintained at ambient storage conditions. The labeled storage requirement for the material states "keep container cool and dry". There is no assurance the ambient condition do not adversely affect the quality of the product. For example, during the storage period, temperatures in the log book were recorded as the following:

Month	Max Temperature °C (°F)	Max. %RH
August 2016	34.7 (94.46)	89.9
September 2016	33.2 (91.8)	90.9
October 2016	32.2 (90.1)	92.0
November 2016	30.3(86.54)	81.4

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