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	7/1/2019-7/5/2019
	FEI NUMBER 3008232264

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Vishal J. Shah, Whole Time Director

FIRM NAME	STREET ADDRESS
Inventia Healthcare Limited	F1- F 1/1, Additional Ambernath MIDC, Ambernath (east)
CITY, STATE, ZIP CODE, COUNTRY Thane, Maharashtra, 421506 India	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 conduct adequate laboratory investigations in accordance with procedure QA/051 *Handling Out of Specification Results* to sustain appropriate conclusions and to propose adequate corrective/preventive actions for the Out Of Specification (OOS) results. These deficiencies are evidenced in the following examples of conditions observed during the review of the related substances testing investigations.

a. The investigation report OOS/145/19 lacked adequate scientific justification and documentation to support conclusions or actions (i.e., data invalidation, and re-test) taken by your firm to handle the out of specification (OOS). For example:

- Your laboratory investigations do not include enough supporting documentation evidencing that the questionable OOS results can be attributed to a possible column problem assignable cause in order to invalidate initial OOS results. Moreover, there is no evidence showing that your firm has addressed the condition through the implementation of effective corrective and preventive actions to avoid the recurrence of the assignable cause.
- The investigations where OOS for the related substances test of the batches number (b) (4) and (b) (4) of (b) (4) (b) (4) Tablets, USP (b) (4) mg attributed to the column use, was not extended to other batches of product analyzed with the same column (i.e., previous batches of product tested using

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Nicole E Knowlton, Investigator Jose A Lopez Rubet, Chemist/Biologist	DATE ISSUED 8/5/2019

X Nicole E Knowlton Investigator Signed By: Nicole E. Knowlton -S Date Signed: 08-05-2019 09:32:59

the same column, analytical test method and technique).

b. The investigation report OOS/169/19 was related to OOS results for the related substances in the released (b) (4) Tablets, USP (b) mg Batches number: (b) (4) (b) (4) and (b) (4). The sample was re-tested with new sample preparation solutions and all the results were within limits. The investigation does not include a re-injection of the original HPLC vial and a newly prepared HPLC vial, from the original sample volumetric flask, to fully investigate the source of the OOS. The questionable OOS results were attributed to a possible column problem.

These investigations were reviewed and approved by your Quality Unit.

OBSERVATION 2

Laboratory records do not include complete records of the periodic calibration of laboratory instruments.

Specifically,

Vibration test was not included in the instrument vendor qualification and internal calibration of the dissolution baths used for testing of finished products and stability samples since the installation of the systems. Additionally, the chemical test with prednisone tablets which is a part of the instrument calibration, including the paddles and baskets, was only performed (b) (4). The Quality Control Unit reviewed and approved the data that supports the calibration of the laboratory dissolution baths during qualification and calibration.

OBSERVATION 3

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,

The controls are inadequate for access privileges for Empower 3, Open Lab and Chromeleon in that the Quality Assurance (QA) department, outside service personnel roles and authorization responsibilities are not included in the procedure QC/GEN/041 *Standard Operating Procedure for Data Access, User Privileges, Electronic Signature and System Policies of Chromatography System and Other Software Based System*.

OBSERVATION 4

Control procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically,

The firm's standard operating procedures QC/INS/028 *Operation and Maintenance of* (b) (4) *Type Stability Chamber* and QC/INS/064 *Procedure for Operation and Maintenance of* (b) (4) *Type Stability Chambers and Operation of IC DAS Software Version 1.2* does not address the cumulative effect of the temperature and relative humidity being out of limits regarding drug products in the stability chambers. The firm does not document corrective actions when temperatures and/or relative humidity level are out of the limits for less than (b) (4).

OBSERVATION 5

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

Specifically,

A significant number of balances and pH meter data print outs do not include complete data. For example: the date the analyst and review person signed the documents and complete identification such as sample number and test reference. Additionally, blank spaces were observed. Some examples include: 1) the worksheet for the sample

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batch number (b) (4) and (b) (4) of (b) (4) Tablets, USP (b) (4) mg for finished product release, 2) calibration records for the dissolution bath systems calibration and 3) the data reports review for the Out Of specification investigations OOS/145/19 and OOS/169/19.

OBSERVATION 6

Employees engaged in the manufacture, processing, packing and holding of a drug product lack the training required to perform their assigned functions.

Specifically,

There is no qualification performed for personnel performing visual inspections of the firm's tablet and capsule products.

Planned Deviation PD/PR/2019/9 was initiated to manually visually inspect four batches of (b) (4) (b) (4) Tablets USP (b) (4) mg instead of using the tablet /capsule inspection machine due to the production load and to meet the dispatch dates. Batch (b) (4) was manually visually inspected between May 30-June 1, 2019 by seven different employees.

No qualification was performed for these visual inspectors. Training records show personnel were trained on PR/GEN/046 *Procedure for Inspection of Tablet/Capsule* which pertains to Acceptance Quality Level (AQL). Additionally, there is no record of the rejects observed during the visual inspection of the batch and the type and quantity of those defects is unknown.

The Reconciliation section of the batch manufacturing record for Batch (b) (4) shows the quantity of tablets rejected during inspection as (b) (4) kg, which was calculated by firm management to be approximately 5200 tablets. The AQL consisted of (b) (4) tablets sampled from (b) (4) containers; 1 tablet was rejected for a major defect and 4 tablets were rejected for minor defects. The AQL for this batch was performed by a Quality Assurance (QA) Junior Officer and verified by a second QA Junior Officer. No qualification was performed for these visual inspectors. Additionally, the position description for the

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reviewer does not list the responsibility to perform AQL.

Firm management confirmed they do not perform qualification for their visual inspectors.

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