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 Industry Information: www.fda.gov/oc/industry	03/07/2022-03/30/2022
	FEI NUMBER 3006271438

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Ronald W. Overhiser, Vice President - Operations and Site Head	
FIRM NAME Novel Laboratories, Inc. d.b.a Lupin Somerset	STREET ADDRESS 400 Campus Drive
CITY, STATE, ZIP CODE, COUNTRY Somerset, NJ 08873-1145	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:

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.

REPEAT OBSERVATION

Specifically,

A. OOS LAB00157, dated 4/16/2021, for (b) (4) Tablets, (b) (4) mcg, (b) (4) ct, (24mo CRT), lot (b) (4) regarded an out of specification for (b) (4) impurity (b) (4) The product expired March 2021. This sample represents (b) (4) lots of (b) (4) Tablets manufactured in 2019. The OOS was confirmed on 4/17/21 and no definitive root cause was identified. It was hypothesized that the most probable cause for the OOS was moisture uptake when the bottle was opened for analysis. An initial FAR was filed on 4/21/21. The Phase II investigation consisted of testing the same lot 8 months later. Your investigation did not test the retains of (b) (4) additional lots manufactured in 2019, which were still within expiry, to ensure they were within specification. The investigation did not evaluate if different packaging was needed (i.e. blister packs) if excessive moisture upon opening a bottle containing (b) (4) ablets which was analyzed the same day, caused the product to be out of specification.

B. LAB00182, dated 9/9/2021, for Oxycodone HCl tablets, CII, 5mg, (18mo. CRT), lot S000268, regarded an out of specification for impurity (b) (4) (b) (4) %, specification NMT0 (b) (4) %). This product expired January 2022. This sample represents (b)) lots of Oxycodone HCl tablets manufactured in 2020. The OOS was confirmed on 9/9/2021 and no root cause identified. Batch S000268 was recalled from the market. Retains from the remaining (b) (4) batches were not analyzed for compliance until two months later on 11/8/2021.

C. LAB00197 and LAB00198, dated 11/8/2021 and 11/10/2021, for (b) (4) (12mo. CRT), lot (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Adetutu M Gidado, Investigator Ko U Min, Investigator Sandra A Boyd, Investigator/NE	03/30/2022

(expiry 7/2022) regarded out of expectation results being converted to out of specification investigations due to OOS assay results obtained during re-analysis for (b) (4) This lot was the last batch in a joint packaging revalidation of (b) (4) and (b) (4) This product has a (b) (4) expiry date. A FAR was initiated on 11/12/21. The OOS was confirmed on 12/17/2021. No root cause identified. The (b) (4) batches of (b) (4) produced after (b) (4) have been either recalled or rejected for unrelated issues. Phase II is still ongoing, (+4 months) and batch (b) (4) is still on the market.

D. No investigation was initiated into the root cause of the Ralstonia Picketti, detected in your (b) (4) system on 5/27/2021 and 6/23/2021. The (b) (4) is used in the manufacturing (i.e., (b) (4) (b) (4) Solution) and cleaning of equipment used in the manufacturing of human drug products (i.e., (b) (4) Capsules, (b) (4) and (b) (4) Tablets (b) (4)).

E. There is no scientific justification for not investigating extraneous peaks which are less than (b) % of the standard response of the swab sample. Extraneous peaks were noted during the cleaning of (b) (4) on 7/9/2021. The equipment was not recleaned and the source of the extraneous peaks was not investigated.

OBSERVATION 2

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

Specifically,

A. You have not documented the qualification of the contract packager for the packaging of (b) (4) Tablets. Although qualified for other products, (b) (4) Tablets is the first (b) (4) product packaged for you by this contract packager starting in March 2021. NL-QA-013.6 Vendor Qualification, effective 7/7/2021 specifies an audit frequency for a contract packager of (b) (4) This contract packager was last audited in 2017. The Quality Agreement with them does not include (b) (4) Tablets.

The Director of Quality stated VPP-01780 Legacy Vendor Qualification Program, dated 7/7/2021, was initiated to assess gaps in their supplier qualification program. Your firm is in the process of evaluating the current vendors against current expectations. These gaps are not reflected in any other quality system, (i.e., CAPA). The current tracker associated with VPP-01780 shows the contract packagers for (b) (4) (b) (4) mg, (b) (4) Capsules, (b) (4) Tablets, and (b) (4) are currently not

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 Industry Information: www.fda.gov/oc/industry	03/07/2022-03/30/2022
	FEI NUMBER 3006271438
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Ronald W. Overhiser, Vice President - Operations and Site Head	
FIRM NAME Novel Laboratories, Inc. d.b.a Lupin Somerset	STREET ADDRESS 400 Campus Drive
CITY, STATE, ZIP CODE, COUNTRY Somerset, NJ 08873-1145	TYPE ESTABLISHMENT INSPECTED Drug Product Manufacturer

approved.

B. Investigations into the SAP discrepancies are currently not being evaluated within the Quality system, see Observation 8. The Associate Director of Supply Chain and Warehouse Operations ((b)) stated they discovered material listed in the SAP system that wasn't physically present in the bin location, approximately 4-6 weeks ago. The Associate Director of Supply Chain and Warehouse Operations stated he is working with SAP to fix the issue, but currently the investigation/evaluation is not documented.

C. There is no procedure for the issuance and reconciliation of documents containing raw data including but not limited to equipment cleaning forms, preventative maintenance forms or incident request forms.

D. Scientific justification could not be provided for not performing microbial testing on the following products:

- (b) (4)
- (b) (4) Tablets, (b) (4) mg, (b) (4) mg
- (b) (4) Tablets, (b) (4) mg
- (b) (4) (b) (4) g
- (b) (4) Tablets, (b) (4) mg
- (b) (4) Tablets, (b) (4) mg
- (b) (4) Capsules, (b) (4) mg
- (b) (4) Capsules, (b) (4) mg, (b) (4) mg
- (b) (4)

E. Change controls covering multiple documents do not contain sufficient detail of the proposed change to allow adequate evaluation of the change prior to implementation. In addition, effectiveness checks of change controls are not performed.

F. Implementation of switching to 100% verification for cleaning on non-dedicated equipment was not handled through a Quality System (i.e. deviation). This change was a commitment made to FDA as a result of the last FDA inspection. Instead, this change was verbally directed downward to mid-level managers in Quality who then requested the swabs to be taken on a sample request sheet.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Adetutu M Gidado, Investigator Ko U Min, Investigator Sandra A Boyd, Investigator/NE	DATE ISSUED 03/30/2022

G. The location listed for (b) (4) USP raw material Lot# (b) (4) staged at the 15/17 Jensen Drive warehouse, was not accurate in the SAP system. During our walkthrough inspection of the 15/17 Jensen Drive warehouse on 03/09/2022, we observed that (b) (4) USP raw material Lot# (b) (4) was assigned a "QA Hold" status due to Out of Specification (OOS) investigation LAB-00190; however, the SAP record shows the current storage location as "0101" which is the 390 Campus Drive warehouse. Your Quality Unit lacks oversight and control of the raw material Lot# (b) (4) which was put on "QA Hold" but moved by warehouse personnel.

OBSERVATION 3

Procedures describing the handling of all written and oral complaints regarding a drug product are not written and followed.

Specifically, your complaint SOP NL-QA-037.10 "Management of Product Quality Complaint" does not outline instructions to initiate investigations when multiple complaints of short/over bottle count for the same batch are received. For example, your firm received twenty (20), seven (7) and seventy-three (73) market complaints for (b) (4) Batch # (b) (4) (b) (4) and (b) (4) respectively regarding short/over counts (complaint dates 11/2020 to 03/03/2022); (b) (4) is packaged in (b) (4) count bottles. In addition, your firm received four (4) complaints for (b) (4) Batch # (b) (4) regarding short/over counts; (b) (4) is also packaged in (b) (4) count bottles. The batch record specification for (b) (4) count individual bottles is NLT (b) (4) and NMT (b) (4) nd your complaint reports state that market complaints for one and/or two short or over counts of tablets per bottle is considered minor and no further actions or investigations are required.

OBSERVATION 4

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

REPEAT OBSERVATION

Specifically,

A. There are no records documenting On the Job training (OJT) for all Operators hired prior to 01/2022. Your SOP No. NL-GN-009.5 "Personnel Training" Effective Date 08/16/2021 states Quality Assurance (QA) "Ensures that personnel have completed required on-the-job training and providing documentation of the same prior to releasing personnel to perform role/task"; however, QA does not have OJT training records of any operators to

justify their release to perform GMP operations.

B. Deviation from SOP No. NL-GN-009.5 Section 6.11.1.1 for training "On GMP regulations (b) (4) or as required, with such frequency to assure that personnel remain familiar with the applicable cGMP requirements" is documented in an email instead of a Quality document. For example, the (b) (4) classroom cGMP training for 2020 was replaced with SOP reading and it was documented and notified to employees through a company email; no quality documentation of this planned deviation is available.

C. Your training SOP No. NL-GN-009.5 does not outline the time required to complete SOP trainings when an "Unsuccessful" assessment is received by the trainee. For example, a compression operator who also cleans drums and pallets received an "Unsuccessful" training for SOP No. NL-QA-001.8 "MANAGEMENT AND TRAINING OF STANDARD OPERATING PROCEDURES" Effective Date 01/04/2022 on 01/31/2022 however, as of 03/10/2022 no retraining for the operator had been completed to obtain a "Successful" assessment. In addition, the same operator received "Unsuccessful" training for SOP No. NL-PR-123 "Operation, Cleaning, Calibration and Preventive Maintenance of (b) (4) Liter (b) (4) Tank (For Solvent System)" Effective Date 11/25/2020 on 09/29/2020; however, "Successful" training was obtained approximately 14 months later, on 11/23/2021.

FACILITY AND EQUIPMENT SYSTEM

OBSERVATION 5

Procedures for the cleaning and maintenance of equipment are deficient regarding sufficient detail of the methods, equipment, and materials used in the cleaning and maintenance operation, and the methods of disassembly and reassembling equipment as necessary to assure proper cleaning and maintenance.

Specifically,

A. The operators do not document start/stop times, amounts of water and/or cleaning solutions used, or number of jets used during the cleaning of manufacturing equipment. There is no assurance that the cleaning is performed as per the firm's approved procedure.

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 Industry Information: www.fda.gov/oc/industry	03/07/2022-03/30/2022
	FEI NUMBER 3006271438

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Ronald W. Overhiser, Vice President - Operations and Site Head	
FIRM NAME Novel Laboratories, Inc. d.b.a Lupin Somerset	STREET ADDRESS 400 Campus Drive
CITY, STATE, ZIP CODE, COUNTRY Somerset, NJ 08873-1145	TYPE ESTABLISHMENT INSPECTED Drug Product Manufacturer

B. Gaps in cleaning of up to 14 days were noted during the review of Form-NL-PR-146-2.3 Regular Cleaning Checklist for Liquid Manufacturing Tanks with (b) (4) (Holding and Manufacturing tanks Capacity (b) (4) iters. On 12/20/2021, the operator executed in part, discharging the waste (b) (4) from the tank using the exit valve. The operator did not continue the cleaning by performing, "Once the (b) (4) from Tank A is drained, closed the discharge valve of Tank A from the PLC", until 1/3/2022. At this point the operator was on step (b) (4) of a (b) (4) step cleaning procedure. Starting and stopping cleaning is not addressed in the cleaning validation.

C. On 3/7/2022, during the walk-through of the (b) (4) drug manufacturing building (b) (4) the logbook for the (b) (4) cu. ft. (b) (4) #0152) stated cleaning was started after manufacturing was completed on 2/24/2022. This cleaning is listed as still in-process within the logbook. However, review of the (b) (4) cleaning checklist shows the only cleaning activity executed was identifying the (b) (4) and room as "To be Cleaned". As dirty hold time for this equipment is based off the logbooks, this equipment would have a dirty hold time of 0 days instead of the (b) (4) days it had to that date.

D. Your firm could not provide supporting documentation such as the original approved method validation protocol MVP-SOAP-CLN-LC and report MVR-SOAP-CLN-LC from 2007, which contain data on linearity, limit of detection, and accuracy/method precision. The data within these documents were used to support the amended in-house cleaning method (CL (b) (4) LC-04) for (b) (4) by swabbing in 2020. Therefore, the actual validation of cleaning method for (b) (4) residues could not be verified.

OBSERVATION 6

Written procedures are not established and followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing, or holding of a drug product.

REPEAT OBSERVATION

Specifically,

A. Determination of equipment sampling sites are not evaluated using a risk-based approach. The swab locations listed in SOP Form NL-VA-002-1.15 Locations and Pictures for Swab Testing, effective Nov. 16, 2021, are not based on a risk assessment to ensure the swab samples, used to verify the cleaning of production/packaging equipment, are based on the hardest to clean areas. For example, NL-PR-148-1.1 Regular Cleaning Procedure

Checklist for (b) (4) L (b) (4) Tank states "*Visually inspect the* (b) (4) (b) (4) (b) (4) . The swab sample site procedure only states to swab the (b) (4) It is unclear whether the other locations were evaluated when determining the swab locations used to verify cleaning of the (b) (4) L tank.

B. The studies in support of campaign cleaning do not ensure lack of build-up and carry-over of contaminants (e.g., degradants or objectionable levels of microorganisms).

1. PRP-01264 Campaign Length Study Protocol for (b) (4) Products is based on a risk assessment. Of the (b) (4) products for which you campaign manufacture, only four were evaluated. Sampling for impurities was not performed prior to the final cleaning for these studies.

2. Campaign manufacturing was performed prior to validating the process. You did not evaluate the lengths of the previous campaigns to ensure the validation encompassed these lengths.

C. There is no procedure for cleaning of the (b) (4) (used for in-process testing during compression). This equipment was observed dirty during a walk-through inspection on March 7, 2022, in building (b) (4) manufacture of (b) (4) drugs.

OBSERVATION 7

Equipment used in the manufacture, processing, packing, or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Specifically,

A. Procedures for (b) (4) Cu. Ft (b) (4) and (b) (4) Cu. Ft (b) (4) requires the attachment of an empty drum to the discharge valve during (b) (4) process to account for leaks. During the walkthrough of the production on 03/07/2021, a drum was observed attached to the discharge/loading chute of a (b) (4) cu feet (b) (4) located in Room (b) (4) The drum was left in this position all through the (b) (4) process. The qualification of the equipment or process was not performed with the drum attached. (b) (4) out-of-specification were reported in drug product that were manufactured in the subject (b) (4)

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900 Fax:(973)331-4969 CRAPHARM1 RESPONSES@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	03/07/2022-03/30/2022 FEI NUMBER 3006271438

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Ronald W. Overhiser, Vice President - Operations and Site Head	
FIRM NAME Novel Laboratories, Inc. d.b.a Lupin Somerset	STREET ADDRESS 400 Campus Drive
CITY, STATE, ZIP CODE, COUNTRY Somerset, NJ 08873-1145	TYPE ESTABLISHMENT INSPECTED Drug Product Manufacturer

B. 100% check-weigher machine ID No. 2017 used for capsule products such as (b) (4) Capsules, USP (b) (4) ng, and (b) (4) Capsules (b) (4) mg and (b) (4) mg was not adequately qualified and/or calibrated for its intended use. Individual capsules of the batches noted above undergo a target weight verification between (b) (4) ng – (b) (4) ng, using machine speed between (b) (4) capsules/hour. (b) (4) point weight verification at (b) (4) ng was performed during the initial qualification and subsequent calibrations. Machine speed was not verified during qualification and is not a part of the calibration schedule. The firm has received about eight complaints for empty or less powder in capsules for (b) (4) products and has since submitted two field alerts for empty capsules.

C. The (b) (4) System used to generate and circulate production and cleaning (b) (4) used in building (b) (4) liquid and solid dosage drug products has the following deficiencies:

1. The first phase of the performance qualification (PQ) of the (b) (4) system was not performed as specified in the approved protocol. The protocol requires a (b) (4) monitoring (sampling and testing) of (b) (4) sites and point-of-use, except for the points before the (b) (4) unit and the laboratory area. A total of (b) (4) sites were identified, but only (b) (4) sites were sampled and tested. No adequate justification was provided for not performing the other sites.

2. Installation/operational qualification report and operational procedure of the (b) (4) states that the storage and distribution system of the (b) (4) was designed to supply (b) (4) nominal of (b) (4) feed with a set point of NLT (b) (4) On 09/03/2021, a low loop supply and return flow alarm was observed a change control was issued to change the flow set point for both return and supply flow from (b) (4) to (b) (4) Another low loop supply and return flow alarm was observed on 09/22/2021, the flow set point for both return and supply flow was then changed from (b) (4) to (b) (4) The flow sensor (FE-602) for return is located (b) (4) the tank and the flow sensor (FE-601) for supply is located (b) (4) distribution loop. No justification was documented for the changes implemented.

3. During the walkthrough of the (b) (4) ystem on 03/07/2022, a green like substance was observed inside the (b) (4) flow meter on the (b) (4) unit of the (b) (4) Though the flow meter is located before the filter on the (b) (4) The presence and impact of the green substance was not examined.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Adetutu M Gidado, Investigator Ko U Min, Investigator Sandra A Boyd, Investigator/NE	03/30/2022

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 Industry Information: www.fda.gov/oc/industry	03/07/2022-03/30/2022
	FEI NUMBER 3006271438

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Ronald W. Overhiser, Vice President - Operations and Site Head	
FIRM NAME Novel Laboratories, Inc. d.b.a Lupin Somerset	STREET ADDRESS 400 Campus Drive
CITY, STATE, ZIP CODE, COUNTRY Somerset, NJ 08873-1145	TYPE ESTABLISHMENT INSPECTED Drug Product Manufacturer

4. On 08/30/2021, 08/31/2021, 10/20/2021, 11/11/2021, 01/06/2022, and 02/25/2022, it was observed that date and time of the Human Machine interface (HMI) of the (b) (4) system did not match the actual date and time. A work order was issued to reset the date and time, but the impact of the resets on the performance of the system was not assessed. Sanitization of the (b) (4) ystem is initiated on the HMI, with a (b) (4) ime set.

OBSERVATION 8

Input to and output from the computer and records or data are not checked for accuracy.

Specifically,

A. During the review of the last (b) (4) inventory reconciliation performed March 2021, it was noted that not all inventory was reconciled, material listed in SAP was missing from the warehouse, and quantities listed in SAP did not match physical quantities. This includes (b) kg of (b) (4) - Standard and (b) (4) kg of (b) (4) isted in SAP but missing from the vault. An investigation was not initiated. In addition, the label inventory is not part of the (b) (4) nventory reconciliation. Furthermore, there is no procedure detailing the execution of the (b) (4) inventory reconciliation of the warehouse.

B. On 3/9/2022, SAP listed 6 different materials as being stored in cold room storage ((b) (4) (b) (4) USP (b) (4) USP (b) (4) (b) (4) USP (b) (4) Upon inspection of the cold room storage, only containers of (b) (4) were being stored.

C. During a walk-through inspection of the warehouse on 3/9/2022, materials stored on a pallet in the building (b) (4) were viewed in SAP to confirm the inventory balance. Two lots of (b) (4) although physically present on the pallet were listed as a zero inventory SAP.

OBSERVATION 9

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.

REPEAT OBSERVATION

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Adetutu M Gidado, Investigator Ko U Min, Investigator Sandra A Boyd, Investigator/NE	03/30/2022

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 Industry Information: www.fda.gov/oc/industry	03/07/2022-03/30/2022
	FEI NUMBER 3006271438

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Ronald W. Overhiser, Vice President - Operations and Site Head	
FIRM NAME Novel Laboratories, Inc. d.b.a Lupin Somerset	STREET ADDRESS 400 Campus Drive
CITY, STATE, ZIP CODE, COUNTRY Somerset, NJ 08873-1145	TYPE ESTABLISHMENT INSPECTED Drug Product Manufacturer

Specifically,

A. One general ID and password is used for IT and Computer System Validation (CSV) departments to access the (b) (4) tablet tester, which is used for the in-process check for (b) (4) and weight of the following products: (b) (4) Tablets (b) (4) Tablets, (b) (4) Tablets, (b) (4) Tablets, and (b) (4) Tablets.

B. Your SOP No. NL-IT-010.0 "GxP Computerized and Automated Systems User Access Management" Effective Date 06/12/2020 states that IT provides system access to users. During the walkthrough inspection of Building (b) (4) production on 03/07/2022, we observed the user login for (b) (4) for Equipment ID# 0991 (used for In-Process testing during compression) for Operators ID#s GN3320040 and Supervisor (b) , however, upon IT record verification, we observed that these Operators were missing from the IT record in Lansweeper.

LABORATORY CONTROL SYSTEM

OBSERVATION 10

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

Specifically,

A. Stability chambers are not periodically temperature mapped and no procedure exists describing how and when to perform temperature mapping. Management stated temperature mapping is only performed during qualification. The CRT chambers (25°C/60%) were last qualified in 2014 and 2015.

B. Weight sets ID# 3346, 3281, 3282, 3346 and 2085 used for (b) (4) verification of balances and scales in the production area has an as found disposition value of "out of tolerance" in June 2021. The last recorded time these weight sets were found within tolerance was in June 2020. These scales and balances are routinely used for dispensing and weighing of materials and/or in-process samples.

OBSERVATION 11

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications, standards and test procedures designed to assure that components conform to appropriate standards of identity,

strength, quality and purity.

REPEAT OBSERVATION

Specifically,

A. The following discrepancies were noted during the review of the procedures associated with the (b) (4) system used in the cleaning and manufacturing of human drug products in building (b) (4)

1. The firm has not demonstrated that the current practice of testing (b) ml of (b) (4) using (b) (4) filtration derives statistically valid colony counts. Of the (b) (4) tests executed by the contract laboratory, CFUs were only detected on 27 plates. This method has not been proven suitable for use/verified at the contract testing laboratory.

2. Action levels for (b) (4) are not based on historical levels. Investigations only take place after the action level is exceeded. As the action level is set at (b) (4) CFUs/ml, an investigation will only take place after the (b) (4) s out of specification.

3. The microbial flora of your (b) (4) system in building (b) (4) is unknown. You do not periodically identify microbial flora. Currently, identification only takes place after alert levels are achieved.

B. Your current analytical test methods for all finished products such as (b) (4) and (b) (4) Tablets, (b) (4) Capsules, and (b) (4) Tablets (Test Methods: FP-358-LC-AS-03, FP-123-AS-02, and FP-161-AS-01 respectively) and APIs such as (b) (4) USP, (b) (4) USP, and (b) (4) (Test Methods: RM-5043-AS-02, RM-5038-AS-01, and RM-5027-AS respectively) do not include verification of the accuracy for sample preparation during assay testing. Your firm's SOP No. NL-QC-011.7 "REQUIREMENTS OF PHYSICAL AND CHEMICAL TESTS" Effective Date 05/07/2018 only requires (b) (4) individual sample preparation with single injection or single absorbance (UV) reading of each assay analysis and does not include verification of the accuracy for all sample preparations for finished products and APIs.

C. Your firm's SOP No. NL-QC-113.0 "INTEGRATION OF U/HPLC AND GC CHROMATOGRAPHIC

DATA" Effective Date 09/29/2021 does not include instructions on how to integrate chromatograms. Analysts routinely set multiple "Minimum area" and "Minimum height" integration events once the Peak width and Threshold are set for the processing method which inhibit integrations; the Impurity and Degradant analysis for (b) (4) Capsules (Test Method FP-123-DEG-00), Batch# (b) (4) had (b) (4) Minimum Area/Height integration events.

D. There is no assurance that the (b) (4) Analyzer (Equipment ID: (b) (4) #01) operates as intended and can accurately assess (b) (4) content for release testing of the Raw Materials and Finished Products. Your SOP No. NL-QC-039.18 "OPERATION AND CALIBRATION OF THE (b) (4) AUTO-TITRATOR AND POTENTIOMETRIC AUTO-TITRATOR" Effective Date 11/08/2021 does not require analysis of a standard that is close to the sample results for an accuracy check. Instead, the firm uses (b) (4) to conduct the accuracy check with an acceptance specification of (b) (4) % to (b) (4) %. However, your specification for multiple finished products such as (b) (4) (b) (4) Solution USP (b) (4) mEq (b) (4) and (b) (4) Solution (b) (4) is lower than (b) (4) %, with range of error for the (b) (4) accuracy check at NMT (b) (4) %.

OBSERVATION 12

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

Specifically, injection and data reconciliations are not performed for the chromatographic and FTIR data obtained in the QC laboratory. Data reviewers only review what is submitted electronically for review for Empower and FTIR and there is no procedure for reconciliation of electronic data outside of the sequence. In addition, there is no procedure for naming data files for FTIR. On 03/07/2022, during our review of electronic data on Instrument ID# FTIR #01 we observed unconventional file names without Lot numbers; it is not evident if the files with unconventional names are official samples and had been reviewed by the datareviewers. In addition, your firm does not review electronic data for standalone equipment including but not limited to the Osmometer, Density Meter, and Viscometer. Review is conducted only of printed data and not of electronic data.

OBSERVATION 13

The written stability program for drug products does not include reliable, meaningful, and specific test methods.

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 Industry Information: www.fda.gov/oc/industry	03/07/2022-03/30/2022
	FEI NUMBER 3006271438

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Ronald W. Overhiser, Vice President - Operations and Site Head	
FIRM NAME Novel Laboratories, Inc. d.b.a Lupin Somerset	STREET ADDRESS 400 Campus Drive
CITY, STATE, ZIP CODE, COUNTRY Somerset, NJ 08873-1145	TYPE ESTABLISHMENT INSPECTED Drug Product Manufacturer

Specifically,

A. Stability samples are not stored in a manner to ensure proper air flow in the stability chambers. During a walk-though inspection of the stability chambers on 3/9/2022 and 3/16/2022, we observed stability samples stored in (b) (4) boxes, (b) (4) owels, (b) (4) lining and (b) (4) lining the wire shelves on which stability samples were placed.

B. NL-AR-005.4 Validation of Assay and Related Compounds Method describes the actions taken to determine specificity of methods used during stability studies. There is no assurance that methods used during stability studies are able to detect all potential impurities as mass balance is not determined or evaluated. This applies to all commercial products manufactured at Lupin.

***DATES OF INSPECTION**

3/07/2022(Mon), 3/08/2022(Tue), 3/09/2022(Wed), 3/10/2022(Thu), 3/11/2022(Fri), 3/14/2022(Mon), 3/15/2022(Tue), 3/16/2022(Wed), 3/17/2022(Thu), 3/30/2022(Wed)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Adetutu M Gidado, Investigator Ko U Min, Investigator Sandra A Boyd, Investigator/NE X Adetutu Gidado Investigator	03/30/2022