DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Food and Drug Administration - New Jersey District, 10 Waterview Blvd, 3rd Floor, Parsippany, NJ 07054 973-331-4900 ORAPharm1_responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	09/10/2020-11/05/2020* FEI NUMBER 3006271438

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ronald W. Overhiser, Vice President - Operations and Site Head

FIRM NAME	STREET ADDRESS
Novel Laboratories, Inc. d.b.a LUPIN	400 Campus Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Somerset, NJ 08873-1145	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:

OBSERVATION 1

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

Specifically, the firm's equipment cleaning and maintenance was found deficient. We observed several non-dedicated equipment utilized for the manufacturing of commercial drug products with 'cleaned' status label contaminated with powder residue and not properly maintained. Examples include, but are not limited to, the following observations made during the inspection:

A. On 9/30/2020, during inspectional walkthrough of building (b) (4) Room # (b) (4), we observed unknown white powder residue inside a (b) (4), Equipment # 0235. The status label of the equipment was identified as "cleaned". Powder residue was observed at several locations inside the equipment including, but not limited to, (b) (4). The (b) (4) were found with visible damage at several locations. The (b) (4) duct and (b) (4) duct were found dirty with unknown powder residue. The firm stated that evaluation of (b) (4) and (b) (4) ducts are not part of routine maintenance activities and hence they were never dismantled since the machine was installed in 2008. This non-dedicated equipment is routinely utilized for the manufacturing of multiple products including Tinidazole Tablets, 250mg & 500mg, Trimethoprim Tablets, 100mg and Voriconazole Tablets, 50 mg and 200 mg.

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B. On 10/1/2020, during inspectional walkthrough of building (b) (4) we observed one used (b) (4) (b) (4) without a unique identification number stored inside the clean equipment storage room. We observed black mold like appearance inside the (b) (4). The drum used for the storage of the (b) (4) contained powder residue at the bottom. Based on the (b) (4) cleaning procedure, the (b) (4) should be product dedicated. The firm could neither confirm which product this (b) (4) belonged to nor provide any documented usage history. The (b) (4), Equipment # 0235 is non-dedicated and utilized for the manufacturing of multiple products.

C. On 10/21/2020, during inspectional walkthrough of building (b) (4) we randomly selected about 10 trays out of (b) (4) trays and observed white powder residue on at least 4 trays of these non-dedicated (b) (4), Equipment # 0351 and 0352, used for the manufacturing of potent and non-potent products. The trays were stored as 'cleaned'. This non-dedicated equipment is utilized for the manufacturing of multiple products such as, but not limited to, Hydrocodone Bitartate/Homatropine Methylbromide Tablets, 5mg/1.5mg, Phenelzine Sulfate Tablets, USP 15mg and Methylergonovine Maleate Tablets, USP 0.2mg.

D. On 10/5/2020, during inspectional walkthrough of building (b) (4), we observed an (b) (4) Capsule filling machine, Equipment # 0247, with powder residue inside the segments for (b) (4) and (b) (4) (b) (4). Rust-like material was found inside (b) (4) tray used for the collection of (b) (4) capsules during filling operation. The status label of the machine was identified as "cleaned". This non-dedicated machine is routinely used for products such as, but not limited to, Temazepam Capsules, 15mg and 30mg; and Trimethobenzamide HCl Capsules, 300mg.

E. On 9/11/2020, we observed three (b) (4) sampling tools without any unique identification number or associated log books stored inside the "Cleaned Equipment Storage Room" at building (b) (4). The QA technician stated that the tools are brand new and did not follow the "New equipment release procedure" before storing inside the manufacturing floor. We found unknown powder residue on the tip of a sampling tool. No log book was available to track the usage of these sampling tools.

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F. On 9/30/2020, during inspectional walkthrough of building (b) (4) we observed a (b) (4), Equipment # 0837, stored with a status label as 'cleaned' dated '5/12/2020'. When the (b) (4) was dismantled, approximately 50ml of water-like liquid dripped from the chamber. Based on our discussion, the manufacturing supervisor stated that the (b) (4) was used for Potassium Chloride Oral Solution and recently moved from building (b) (4) for storage. The logbook associated with this (b) (4) was initiated on 01/14/2020. We observed five entries in the logbook dated (b) (4) and (b) (4) for regular cleaning, 05/05/2020 for qualification; 05/05/2020 for swabbing for (b) (4) detergent, and (b) (4) for regular cleaning after a preventive maintenance activity. No one could explain how the liquid was present inside the (b) (4) chamber as it was cleaned and sanitized about (b) (4) back.

G. On 9/25/2020, during inspectional walkthrough of building (b) (4) we observed water droplets inside a (b) (4) tank, Equipment # 2037, utilized for the manufacturing of Potassium Chloride Oral Solution USP 20%, (b) (4). The status label of the tank was identified as "cleaned". In addition, the firm could not provide any studies to support the current "(b) (4)" clean equipment hold time.

H. On 9/25/2020, during inspectional walkthrough of building (b) (4) we observed rust-like appearance on the lid (b) (4) of a (b) (4) tank, Equipment # 0927, utilized for the manufacturing of Potassium Chloride Oral Solution USP 20%, (b) (4) We observed unknown powder residues inside the tank. The status label of the tank was identified as "cleaned".

I. On 10/1/2020, during inspectional walkthrough of building (b) (4) we observed a (b) (4) hose utilized for the supply of (b) (4) stored in the equipment storage room. The metal tip was found with rust-like appearance. This hose is used to bl(b) (4) after cleaning.

J. On 10/1/2020, during inspectional walkthrough of building (b) (4) we observed three (b) (4) without any usage logs. Two of them, equipment # 0619 and # 0049 were found with dirty (b) (4).

The manufacturing supervisor stated that the (b) (4) were used for (b) (4) operations for Misoprostol Tablets, 0.1mg and 0.2mg and Methylphenidate Chewable Tablets 2.5mg, 5mg and 10mg as these products require not more than (b) (4) conditions. Cleaning and maintenance history were not available for these (b) (4). The firm does not have a written procedure for operating instructions, cleaning and maintenance of these (b) (4).

K. On 9/30/2020, during inspectional walkthrough of building (b) (4) we observed rust-like appearance on (b) (4) lid (b) (4), Equipment # 0039. The rusted lid (b) (4) were found exposed to the inside part of the blender. The blender was documented as "cleaned".

L. On 9/11/2020, during the packaging operation of Potassium Chloride Oral Solution, USP, batch S001068, we observed leakage of bulk solution from a storage tank. The bulk solution was found leaking onto the floor. A Stainless-Steel container was placed under the leak to collect the leaking solution while the packaging process was on-going. A maintenance work order to correct the malfunction was never initiated.

M. On 10/20/2020, during inspectional walkthrough of building (b) (4) we observed a non-dedicated (b) (4) Tablet Press, Equipment # 0148, with powder residue inside (b) (4), (b) (4) and (b) (4). The status label of the Tablet Press was identified as "cleaned". The manufacturing operator was in the process of setting up the equipment for an upcoming product after QA release.

N. On 9/11/2020, significant amount of powder was observed on the ceiling (on top of HEPA filter screens) of process room (b) (4) Production equipment (b) (4) size (b) (4) (equipment ID: 0629) is housed in this room. Section 6.1.2.12 of the room cleaning SOP (No. NL-PR-083.10, Process Room & Equipment Cleaning Procedure: Manufacturing & Packaging, Version 10, Effective Date: 7/15/2019) requires (b) (4). On 9/14/2020, operator (b) (6) stated he routinely performs regular cleaning of the room (b) (4) for which ceiling is (b) (4). He stated he is

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not provided the (b) (4) . He stated these areas i.e. (b) (4) are not cleaned by (b) (4) during regular cleaning. This room is used to manufacture multiple products such as Hydrocodone Bitartrate and Acetaminophen tablets, Potassium Chloride ER Tablets, and Gavilyte G etc.

OBSERVATION 2
REPEAT OBSERVATION

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. The firm's contract testing laboratory reported an OOS result of (b) (4) ppb for TOC analysis (specification: NMT (b) (4)) for (b) (4) collected on 06/24/2019 from the (b) (4) , Site# (b) (4) located in manufacturing area of Building (b) (4) The firm failed to initiate an investigation for this OOS result until approximately 1 year later on (b) (4) (# LAB-00046) and concluded in the investigation report stating, *"As per the investigation, a review of online TOC readings, for 06/23/2019, 06/24/2019 and 06/25/2019, revealed that the TOC readings were within limit. The root cause does not seem to be related to the operation of* (b) (4) *system or method used for testing. It is more likely that the sample was contaminated during collection / transportation. Based on the acceptable results for other POU's, it can be concluded from the investigation that it is an isolated event and that the OOS TOC result was most likely due to sample contamination during collection / transportation. There was no impact as no product was processed with* (b) (4) *from* (b) (4) *since the last passing TOC result."*

The Quality Unit failed to investigate the following:

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1. The Quality Unit failed to review the TOC print outs collected from the return loop, (b) (4) . The Quality Unit reviewed the (b) (4) entered TOC data by the operators into the "(b) (4) – (b) (4) log book", book # 027 issued from 04/24/2019 to 09/17/2019 but never compared the accuracy with the print outs. A review of TOC print outs, which are the raw data of TOC readings, revealed that failed TOC results were disregarded, and incorrect data was entered into the logbook. This discrepancy was identified at the time of inspection.

Date	Reading as per Return loop On-line TOC analyzer print-out - Equipment # (b) (4) (Action Limit – (b) (4))	Documented reading of TOC on "(b) (4) (b) (4) System - (b) (4) logbook" (Action Limit – (b) (4))
06/13/2019	(b) (4) ppb	(b) (4) ppb
06/20/2019	ppb	ppb

2. The Quality Unit failed to perform an impact assessment of all products manufactured at the facility during this period. A review of on-line TOC analyzer print-outs revealed multiple failures from 06/13/2019 to 07/26/2019 in the return loop of (b) (4) Water System as shown below:

Date	Time	Reading as per Return loop On-line TOC analyzer - (b) (4) (Action Limit – (b) (4))
06/13/2019	7:11 AM to 8:02 AM	(b) (4) ppb
06/19/2019	8:15 AM to 10:38 AM	ppb
06/20/2019	3:52 AM to 8:22 AM	ppb
07/1/2019	9:57 AM to 10:44 AM	ppb
07/26/2019	6:43 AM to 7:20 AM	ppb

3. The Quality Unit shared the responsibility with Operations for the review of (b) (4) Water analytical results received from the Contract Testing Laboratory. The OOS result received by the Validation Manager were not logged in and hence no investigation was initiated for (b) (4) by the Quality Unit.

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B. OOS-19-023 was initiated on 06/13/2019 to probe the OOS results obtained during cleaning verification analysis associated with Orphenadrine Citrate ER Tablets, 100 mg USP, batch# S900734. Orphenadrine citrate residue results of (b) (4) µg/swab for the (b) (4) µg/swab for (b) (4) and (b) (4) µg/swab for (b) (4) samples of the (b) (4) Tablet Press (Equipment ID# 0626), did not meet the established cleaning limit of NMT (b) (4) µg/swab. The reinjection of the original vial and (b) (4) samples confirmed the initial OOS and no assignable cause could be identified for the failure. During the review of chromatograms from initial analysis a (b) (4) peak was observed at (b) (4) run time (~ (b) (4) that was not integrated in sample swabbed from (b) (4). Also peak at ~ (b) (4) in (b) (4) sample was not integrated. No further investigation was performed to identify the peaks. Multiple unknown peaks were also observed in samples swabbed from (b) (4) (b) (4) and (b) (4) The investigation is silent on the identity of the unknown peaks in cleaning validation analysis. From (b) (4), the firm conducted (b) (4) cleaning validation studies and (b) (4) failed to meet acceptance criteria. Manufacturing investigation CFI-OOS-19-023 was initiated along with CFI-OOS-19-060 to investigate CV failures for Orphenadrine citrate residue results generated on (b) (4) respectively. The manufacturing investigation focused on the cleaning method and attributed the failure to steps related to the cleaning of the (b) (4) for the (b) (4) Tablet Press and did not address to investigate the source of unknown peaks in the chromatograms. The investigation concluded that Orphenadrine Citrate tablets is a (b) (4) -based product and is hard to clean from the (b) (4) CAPA-00202 was initiated on 5/31/20 to update SOP NL-PR-106 to provide an improved cleaning method for removing Orphenadrine Citrate from the (b) (4) (b) (4). SOP NL-PR-106 was updated in June of 2020. The Hydrocodone bitartrate/APAP Tablets USP (7.5/325mg-S900294, S900295 and S900471; 10/325mg – S900472) batches were manufactured (between (b) (4)) without verifying cleaning through swab results remains questionable.

Date Manufactured	Batch	Swab Result		Deviation	Root Cause/CAPA
		µg/cm²	Limit		
(b) (4)	RBMP-076-098	(b) (4)	(b) (4)	*Failed* DEV-19-002,	

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(b) (4)		(b) (4)		Recleaned, passed	*Insufficient Cleaning/3 CV to be continued*
	RBMP-076-098	(b) (4)	(b) (4)	Pass	N/A
	(b) (4) batches of Hydrocodone bitartrate/APAP Tablets USP				
	S900353, S900354, S900375	***No swab taken and not reported***			*Failure to implement CAPA, No deviation initiated*
	(b) (4) batches of Hydrocodone bitartrate/APAP Tablets USP				
	S900473 S900474	(b) (4)	(b) (4)	Pass	N/A
	(b) (4) batches of Hydrocodone bitartrate/APAP Tablets USP				
	S900732, S900733, S900734	(b) (4)	(b) (4)	*Failed,* OOS-19-023	*No CAPA initiated*
		(b) (4)	(b) (4)	*Recleaned, Fail*	
		(b) (4)		*Recleaned, Pass*	
	S900858, S900859	(b) (4)	(b) (4)	Pass	N/A
	S901106, S901107, S901108, S900906	(b) (4)	(b) (4)	*Failed,* OOS-19-060	Difficult to clean the (b) (4) -based formulation/ CAPA to update cleaning procedure
		(b) (4)		*Recleaned, Pass*	

C. OOS-19-028 was initiated on 06/20/2019 to probe the OOS results obtained in swab samples from (b) (4) and the (b) (4) Pan on the (b) (4) Capsule Weight Checker (ID #2017) following cleaning verification testing for Trimethobenzamide HCl Capsules, USP 300mg batch S801333. Samples were swabbed after cleaning (b) (4) Capsule weight checker. OOS results of (b) (4) µg/swab and (b) (4) µg/swab were obtained for samples swabbed from (b) (4) (b) (4) and (b) (4) Pan, respectively, against a specification of (b) (4) /swab cleaning limit.

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The (b) (4) of the original vial and (b) (4) samples confirmed the initial OOS and no assignable laboratory error could be identified for the failure. During the review of chromatograms from initial analysis unknown peaks at (b) (4) and (b) (4) were observed in multiple samples. Additionally, unknown peaks at (b) (4) and (b) (4) were observed in swab samples from (b) (4) (b) (4) and (b) (4) Pan along with OOS results for Trimethobenzamide HCl residue. The residue limits were at (b) (4) of the specification for swab sample from (b) (4) (b) (4) /swab). The investigation concluded that the failure is due to improper (b) (4) cleaning of equipment. The equipment was recleaned and again samples were swabbed for determination of Trimethobenzamide HCl residue. Unknown peaks were again observed at (b) (4), (b) (4) and (b) (4) in chromatograms from (b) (4) after recleaning. No further investigation was performed to identify the peaks. The firm's procedure SOP No. NL- QC-023. 14- Laboratory Investigations, Section 2.6.3 deficiently states that investigation is only required when (b) (4) .

A cross-functional investigation (CFI-OOS-19-028) was initiated to identify the root cause. Based on investigation it was identified that the capsule weight checker would accumulate powder and should be completely dismantled during each cleaning.

The equipment was utilized for the processing of Flucytosine Capsules, USP 250mg (Batch S900123) and the weight checker parts were not dismantled for cleaning prior to the processing of Trimethobenzamide HCl Capsules, USP 300mg, Batch S801333. The investigation was not extended to evaluate the presence of Flucytosine contamination in Trimethobenzamide.

In addition, the analytical method used in determination of Trimethobenzamide HCl residue was not validated in appropriate ranges for linearity and accuracy to cover the initial and current MAC concentrations of (b) (4) (from 01/21/11-05/27/20) and (b) (4) (since 05/27/20) as detailed in Observation 4A, thus giving no assurance that the residue amounts reported from cleaning verification residues are accurate.

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D. On 3/17/2020, the firm received a complaint regarding the presence of a foreign particle embedded on Hydrocodone/Acetaminophen Tablets 10mg/325mg, batch S901339. Based on the firm's investigation, CN-000073, the black particle was identified as (b) (4) rubber containing a (b) (4) filler. The root cause was identified as loose black particles shedding from a mount of the (b) (4) used during manufacturing process. Upon examination of the (b) (4), Equipment ID # 819, which was utilized for manufacturing of the subject bulk batch S901086 on (b) (4), the firm identified that the mounts under the (b) (4) had an appearance of shedding particles. During handling of drums while (b) (4) operation, the particles could fall into the blend, and move forward to compression, encapsulation or packaging of finished product. This (b) (4) was identified as a non-dedicated machine utilized for multiple products. The firm neither expanded the investigation to (b) (4) other batches of Hydrocodone/Acetaminophen Tablets 10mg/325mg of the same campaign, nor other products manufactured using this (b) (4). It was noted that (b) (4) is also used in GaviLyte N manufacturing and similar contaminants were observed during in-process inspection of packaging operation (DEV-SO-859-19-0024 and DEV-SO-859-19-0025).

E. The firm received a complaint (DPC-SO-851-19-0007) on January 7, 2019 regarding the presence of dark grayish-blue specks in the product GaviLyte N (Lemon), batch S801021 (Expiry September 2021). Based on the investigation, the external laboratory identified the dark specks as red-brown particles of metallic nature primarily found in tin corrosion products. The investigation concluded that the foreign material was most likely introduced after the batch left from the facility. It was noted that multiple (five) incidents were reported during in-process check during packaging of GaviLyte products which were identified as metal contaminants. The firm could not identify a proper root cause on 3 out of 5 incidents. The firm does not have (b) (4) in the packaging line utilized for GaviLyte products. The firm manufactured about (b) (4) batches between 2019 to 2020.

Deviation #	Batch	Date of packaging	Nature of observation

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DEV-SO-859-19-0013	S900913	07/18/2019	Black specks found during in-process check. Inspection of filler showed that the (b) (4) was scrapping the inside of the (b) (4). Batch was destroyed. Additional in-process check initiated.
DEV-SO-859-19-0015	S900958	07/25/2019	Black specks found during in-process check. Inspection of filler showed that the (b) (4) was scrapping the inside of the (b) (4). Batch was destroyed. Additional in-process check initiated.
DEV-SO-859-19-0020	S901141	08/28/2019	A single black particle during in-process check. The black particle was later discarded inadvertently, so could not identify the particle. A definitive root cause could not determine. Batch was released after discarding the bottles prior to the observation.
DEV-SO-859-19-0024	S901503	11/12/2019	Foreign particles were identified during in-process checks which was identified as fibrous plant matter, rusted (b) (4) steel, black piece of (b) (4) and (b) (4) filler, and (b) (4) steel particle. Discarded the prior filled bottles and rest of the batch was released. A definitive root could not be determined.
DEV-SO-859-19-0025	S901502	11/14/2019	Foreign particles were identified during in-process checks which was identified as fibrous plant matter, rusted (b) (4) steel, black piece of (b) (4) and (b) (4) filler, and plain (b) (4) steel particle. Discarded the prior filled bottles and rest of the batch was released. A definitive root could not be determined.

F. The site initiated an OOS investigation (# LAB-00014) on 2/20/2020 when Nystatin Topical Powder, USP 100,000 units/gram (15g and 30g) batches S801331 (CRT, (b) (4), TB502205) and S800703 CRT 18M (T85023002) failed specifications for antimicrobial assay. The contract testing lab generated the microbial assay value of: (b) (4)% and (b) (4)%, (Limit: (b) (4)). Since then the site has not tested any Nystatin subsequent batches for ongoing stability and the investigation remains open. These are (b) (4) stability batches that represent the actual product in the market. Deficiencies observed in LAB-00014 include:

1. OOS results were discovered on 2/18/2020. The site completed (b) (4) hypotheses tests and did not find a conclusive root cause. During Hypothesis (b) (4) the site prepared the new samples from the same impacted batches and confirmed the original results with some variability. However, the site

continued testing of the samples (expired and R&D batches) for Hypothesis (b) (4). The investigation remains open as of 09/24/2020.

2. The site did not qualify this particular contract testing lab and did not have a quality agreement in place at the start of inspection on 9/10/2020.

G. Out of Expectation OOE LAB00009 was initiated on 2/14/2020 when extraneous peaks were observed greater than the unknow limit (NMT (b) (4)) during dissolution testing of Quinapril HCl and Hydrochlorothiazide Tablets, 10 mg, /12.5 mg, Batch # S900101 12M CRT, S900102 12M CRT, S800861 18M CRT samples. These peaks were observed in all the dissolution samples. The extraneous peaks were observed at (b) (4) time (b) (4) at (b) (4) nm for hydrochlorothiazide and at (b) (4) time (b) (4), (b) (4), (b) (4), (b) (4) at (b) (4) nm for quinapril. The site concluded the analyst did not (b) (4) the dissolution samples as per test procedure. However, the analyst's notebook pages indicated the samples were (b) (4) as per test procedure.

H. Multiple OOSs were reported for microbiological tests, TOC and (b) (4) from routine water sampling of (b) (4) Water System of building (b) (4) between 6/24/2019 to 9/9/2020. Each OOS investigation was concluded as isolated incidents. The incidents were not evaluated in the context of multiple related or similar OOS excursions. (b) (4) Water from building (b) (4) is utilized for the manufacturing of Potassium Chloride Oral Solution USP 20%, (b) (4) and for cleaning of many manufacturing and packaging equipment utilized for (b) (4) and (b) (4) oral products. The firm's on-line conductivity analyzer of return loop, (b) (4) recorded numerous excursions above (b) (4) (action limit: (b) (4) from June 2019 to June 2020. The firm did not consistently track the actions taken during online TOC excursions those are above alert and action limits. The Quality Unit never initiated any deviation nor investigated these excursions.

The following OOSs listed below indicates a continuous trend of microbial contamination in the (b) (4) Water System:

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ronald W. Overhiser, Vice President - Operations and Site Head

FIRM NAME	STREET ADDRESS
Novel Laboratories, Inc. d.b.a LUPIN	400 Campus Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Somerset, NJ 08873-1145	Drug Product Manufacturer

1. 06/24/2019: The firm's Contract Testing Laboratory reported an Out of specification result of (b) (4) ppb for TOC analysis (specification: NMT (b) (4)) for (b) (4) Water collected on 06/24/2019 from a Point of Use, (b) (4) , Site# (b) (4) located at Production Room # (b) (4) in Building (b) (4). The firm initiated an investigation, LAB-00046 only on 7/25/2019 due to the delay in receiving the results from the Contract Testing Laboratory. Based on the firm's investigation, the root cause does not seem to be related to the operation of (b) (4) Water System or method used for testing and it was more likely that the sample was contaminated during collection / transportation. It was noted that the on-line TOC readings were above specification on multiple days between 6/13/2019 and 7/26/2019 as detailed under observation 1(2A). These excursions were not evaluated in the investigation, LAB-00046. No CAPA was proposed. The investigation remains open as of 10/2/2020 (approximately (b) (4)).

2. 04/01/2020: The firm's Contract Testing Laboratory reported an OOS for (b) (4) (b) (4) ((b) (4)) in water samples taken from the sample (b) (4) Site # (b) (4) /SV-601 which is located (b) (4) . The sample (SV601-040120) was collected on 04/01/2020 and the (b) (4) reported was (b) (4) cfu/mL (Specification: NMT (b) (4)). The firm was made aware of the OOS result on 04/06/2020, however, the firm failed to initiate an investigation.

3. 4/23/2020: Water sample collected on 04/22/2020, from Site # (b) (4) /SV-304, located (b) (4) , tested positive for total (b) (4) (Limit: (b) (4)). The firm's investigation, LAB-00044 does not identify the source of (b) (4) complex. During review of maintenance records of (b) (4) Water System, it was noticed that on 5/6/2020, a service was performed by the external service company for (b) (4) Water System and fixed a steady leak from (b) (4) tank. In addition, the service company noted that the (b) (4) was leaking from (b) (4). This activity was never logged into the Equipment/Utility/Facility Logbook -(b) (4) # 0697, which is used for the documentation of maintenance activities of (b) (4) Water System. The Quality Unit was aware of these defects and still concluded that "*There were also no known physical defects in the water distribution system which could have caused contamination of the incoming water supply*". No CAPA was proposed.

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CITY, STATE, ZIP CODE, COUNTRY: Somerset, NJ 08873-1145	TYPE ESTABLISHMENT INSPECTED: Drug Product Manufacturer

4. 06/03/2020: The firm's Contract Testing Laboratory reported an OOS for (b) (4) (b) (4) ((b) (4)) in water samples taken from the sample (b) (4) Site # (b)(4) SV-601 which is located (b) (4) . The sample (SV601-060320) was collected on 06/03/2020 and the (b) (4) reported was greater than (b) (4) cfu/mL (Specification: NMT (b) (4)). Investigation, LAB-00049 was initiated to probe the Out of specification results obtained for (b) (4) plate count for the water sample site # (b)(4) SV601-040120 collected on 04/01/2020 ((b) (4) cfu/mL) and SV601-060320 on 06/03/2020. The contract testing laboratory identified (b) (4) (Gram-negative) in the sample collected on 04/01/2020 and (b) (4) in the sample collected on 06/03/2020 from the same sampling (b) (4). The firm deficiently concluded that the risk is minimal since the organisms were detected prior to (b) (4). However, historical data shows that (b) (4)) was identified in the water samples collected on *10/31/2019* from user points after (b) (4) located in the manufacturing area, ((b) (4) ((b) (4) CFU/ mL), (b) (4) ((b) (4) CFU/ mL), (b) (4) ((b) (4) CFU/ mL) and (b) (4) ((b) (4) CFU/ mL). This contradicts the firm's conclusion that (b) (4) disinfection can eliminate the gram-negative organisms from the water system. No CAPA is initiated. The investigation remains open as of 10/2/2020 (approximately (b) (4)).

5. 09/09/2020: The firm's contract laboratory reported an OOS for (b) (4) on 09/17/20 for sample collected on 09/09/20 (Result (b) (4) CFU/ml, Limit NMT (b) (4) CFU/ml) from a Point of Use - (b) (4) . An OOS was opened (LAB-00096) to investigate the root cause of the failure. The investigation remains open.

I. The site initiated (b) (4) Out of Expectation Investigations (LAB 00051 and OOE 19-016) for extraneous peaks observed in Hydrocodone and Homatropine Tablets, 5mg /1.5 mg commercial release and stability samples as below:

   a. LAB 00051 was initiated on 6/19/2020 when extraneous peaks were observed during release testing (for dissolution) in three batches of Hydrocodone and Homatropine Tablets, 5mg /1.5 mg CII USP for batch # S000577, S000579 and S000580.

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b. OOE 19-016 was initiated on 9/6/2019 when an extraneous peak was observed during stability testing (for dissolution) in one batch (S900437 3M CRT) of Hydrocodone Bitartrate and Homatropine Methylbromide Tabs USP 5mg/1.5 mg. Based upon further spectra studies utilizing a (b) (4) detector, the site concluded the spectra of the extraneous peak matches with the spectra of Acetaminophen.

In LAB 00051, the site identified contaminated glassware as the potential root cause; however, the investigation does not explain how a single contaminated pipette can produce extraneous peaks with different peak areas in some samples but not others. The investigation did not include a historical review of similar OOE investigations, such as OOE 19-016 pertaining to the same product.

Other investigations initiated for extraneous peaks include:

OOS No.	Product Involved	Batches Impacted	Brief Summary
OOS-19-027	Gavilyte-C, Gavilyte-G	S900762, S900763, S900272_3M CRT (Gavliyte G)	OOS result for % Chloride was observed during (b) (4) Analysis and (b) (4) for CU (Chloride) did not meet the specification. Extraneous peak of % was observed during PEG analysis during CU and Assay analysis
CFI-DEV-17-212	Cleaning verification of HCB/APAP 10mg/300 mg & (b) (4) (b) (4) (b) (4) .Equipment ID#0340	S700755	Extraneous peak at RT (b) (4) min did not meet the specification for APAP residue. Sample Area: 409821; Standard Area: (b) (4)

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CFI-DEV-17-216	Cleaning Verification HCB/APAP 10 mg/325 mg equipmentID#0894	S700837	OOS result obtained during cleaning verification, the APAP residue was (b) (4) µg/swab did not meet specification of (b) (4) /swab
OOE-19-012	Dexmethylphenidate HCL, USP 2.5 mg	S701150A-18M CRT	An Extraneous peak with (b) (4) % at (b) (4) min found during Dissolution analysis
OOE-19-024	Oxycodone HCl Tabs, 30 mg	S901500 BU	An extraneous peak (at (b) (4) %) at about (b) (4) during (b) (4) analysis
OOE-19-025	Dexmethylphenidate HCL, USP 2.5 mg	M16590A CRT 63M	(b) (4) extraneous peaks ranging from approx. (b) (4) (b) (4) % were observed during dissolution testing of vessel 1
LAB-00009	Quinapril HCTZ 10/12.5mg x 500ct	S900101	Out of Expectation (extraneous peak) during dissolution analysis for Quinapril HCl and Hydrochlorothiazide Tablets, 10 mg /12.5 mg, Batch # S900101 12M CRT, S900102 12M CRT, S800861 18M CRT
LAB-00051	Hydrocodone Homatropine Tabs 5/1.5mg CII	S000577	Extraneous peaks were observed at (b) (4) time about (b) (4) and (b) (4) during dissolution testing for Hydrocodone and Homatropine Tablets, 5mg /1.5 mg CII USP for batch # S000577, S000579 and S000580

J. Deviation DEV-00302: This Deviation investigation was initiated after the temperature excursion of 102°F was observed for the (b) (4) Refrigerator ID#0493 (normal temp (b) (4)) in the Building (b) (4) Warehouse from 07/31/2020 to 08/18/2020. The warehouse is maintained at a controlled room temperature but the cooling fan in the refrigerator malfunctioned and the refrigerator reached over 100°F. The Deviation DEV-00302 was created on 08/07/2020 and it stated that the Date of Discovery as 08/05/2020 and the Date of Occurrence as 08/01/2020 however, the samples from the Refrigerator ID#0493 were removed on 08/04/2020 (1 day earlier than the noted Date of Discovery) and the Work Order was requested on 08/07/2020 (8 days after the excursion). As of the deviation

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due date 09/18/2020, no investigation was performed and the impact analyses of the retain samples that were stored above (b) (4) for (b) (4) were not conducted. The retain refrigerator contained (b) (4) Batches of various Raw Materials and APIs and (b) (4) batches of Finished Product Voriconazole for Oral Suspension (b) (4).

OBSERVATION 3

The written stability program is not followed.

Specifically, analytical testing of the (b) (4) stability batches is not completed as required under SOP (No. NL-ST-001.4, Administration of Stability Program, Effective Date: 2/6/2020). Section 6.10.1 of this SOP requires that testing of the stability samples must be completed within (b) (4) of the pull date. However, as of 9/28/2020 stability testing of the following (b) (4) batches is still pending.

Name of the Product	Batch#	Storage Condition	Time Point	Scheduled pull date	Date pulled	Days since pulled and 9/28/2020
Nystatin Topical Powder, USP 100,000 Units/Gram	S801331	(b) (4)°C/(b) (4)%RH (CRT)	(b) (4)			
Nystatin Topical Powder, USP 100,000 Units/Gram	S800703	(b) (4)°C/(b) (4)%RH (CRT)				
Nystatin Topical Powder, USP 100,000 Units/Gram	M17023A	(b) (4)°C/(b) (4)%RH (CRT)				
Nystatin Topical Powder, USP 100,000 Units/Gram	S900145	(b) (4)°C/(b) (4)%RH (CRT)				

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Nystatin Topical Powder, USP 100,000 Units/Gram	M17024A	(b)(4)°C/(b)(4)%RH (CRT)
(b) (4)		(b)(4)°C/(b)(4)%RH (CRT)
Nystatin Topical Powder, USP 100,000 Units/Gram	S800290	(b)(4)°C/(b)(4)%RH (CRT)
Methylphenidate Hydrochloride Tablets, USP 10mg CII	S901607	(b)(4)°C/(b)(4)%RH (CRT)
Nystatin Topical Powder, USP 100,000 Units/Gram	S901264	(b)(4)°C/(b)(4)%RH (CRT)
Nystatin Topical Powder, USP 100,000 Units/Gram	S901265	(b)(4)°C/(b)(4)%RH (CRT)
Nystatin Topical Powder, USP 100,000 Units/Gram	S900493	(b)(4)°C/(b)(4)%RH (CRT)
Nystatin Topical Powder, USP 100,000 Units/Gram	S900492	(b)(4)°C/(b)(4)%RH (CRT)
(b) (4)		(b)(4)°C/(b)(4)%RH (CRT)
		(b)(4)°C/(b)(4)%RH (CRT)
		(b)(4)°C/(b)(4)%RH (CRT)
		(b)(4)°C - (b)(4)°C (Long Term)

(b) (4)

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(b) (4)		(b)(4)°C/(b)(4)%RH (CRT)	(b) (4)
Nystatin Topical Powder, USP 100,000 Units/Gram	S800703	(b)(4)°C/(b)(4)%RH (CRT)	
Generic Osmoprep	S090002	(b)(4)°C/(b)(4)%RH (CRT)	
Generic Osmoprep	S090002	(b)(4)°C/(b)(4)%RH (ACC)	
Nystatin Topical Powder, USP 100,000 Units/Gram	S900145	(b)(4)°C/(b)(4)%RH (CRT)	

Other deficiencies observed in stability testing include:

- Approximately (b)(4) stability samples were not tested within the (b) (4) period.
- Approximately (b)(4) samples were tested (b) (4) days after the scheduled test completion date.

Most of the batches in the aforementioned table are (b) (4) stability batches that represent the actual product in the market. During the year of 2019, the site manufactured (b)(4) Nystatin commercial batches as below:

Product Info	Batch No.	Expiry date
(b) (4)		Jun/2021
		Jun/2021
		Jul/2021
		Jul/2021
		Jul/2021
		Jan/2021

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(b) (4)	Jan/2021
	Jan/2021
	Apr/2021
	Apr/2021
	Apr/2021

OBSERVATION 4

The accuracy and sensitivity of test methods have not been established.

Specifically,

A. The Maximum Allowable Carryover (MAC) concentration limits for the products listed below were updated on 5/27/2020. On review of the analytical method validations, it was noted that the validated range did not meet the requirements for the cleaning verifications performed until 5/27/2020. The analytical methods did not cover the linearity and accuracy range to meet the specification thus giving no assurance for the reliability of results reported for the cleaning verification studies performed until 5/27/2020 for products listed in Table below.

The validation ranges are listed below based on the firm's procedure SOP No. NL-AR-008.3- 'Validation of Cleaning Method'. Section 5.3.2 on linearity, Sections 5.3.5.3 and 5.3.7.4 on accuracy states to cover concentrations from Quantitation Limit (QL) to about (b) (4) of the cleaning limit.

Product/Effective dates	MAC µg/cm² Initial	Validation range per SOP requirement	Validated Range Linearity	Range not covered in current Validation

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		Linearity / Accuracy µg/cm² (QL to (b) (4))	Linearity µg/cm²	Accuracy µg/cm²	
Dexmethylphenidate HCl Tablets ((b) (4) (b) (4)) (b) (4) (b) (4))	(b) (4)	(b) (4)	(b) (4)	(b) (4)	
Methylphenidate HCl Tablets ((b) (4) (b) (4))					
Temazepam Capsules (b) (4)) *((b) (4))					
Trimethobenzamide HCl Capsules * ((b) (4)) ((b) (4))					
Phenelzine Sulfate Tablets ((b) (4) (b) (4)) ((b) (4))					

B. The analytical method transfer performed for Degradation Products (impurities test) by HPLC for ANDA 065398 Azithromycin Tablets USP 250mg, 500mg, and 600mg developed at Lupin Limited's Goa, India site failed to meet the established transfer acceptance criteria for Single Max Unknown Impurity (Specification: Mean Value Difference (b) (4) . As per the firm's transfer protocol no evaluation was done to determine why the Somerset location had significantly lower impurity results.

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Despite the failure in acceptance criteria this method was adopted at the Somerset location and used to test the exhibit batches for release Batch# S090015 and stability Batch#s S090016 and S090017 for 250mg.

Single Max Unknown Impurity Specification NMT (b) (4)			
Acceptance Criteria: Mean Value Difference (Δ) Δ(b) (4)			
Batch# G990099 (250mg)		Batch# G990095 (600mg)	
(b) (4)	Somerset	(b) (4)	Somerset
(b) (4)%	BQL ((b) (4))	(b) (4)%	BQL ((b) (4)%)
%	BQL ( )	%	BQL (%)
%	BQL ( )	%	BQL (%)
%	BQL ( )	%	BQL (%)
%	BQL ( )	%	(b) (4)%
%	BQL ( )	%	%
Mean		Mean	
%	BQL ( )	%	%

OBSERVATION 5

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

Specifically,

The MAC values for the products listed in Table below were updated on 5/27/2020. The analytical method validations were performed covering the initial range. On revision of MAC values the analytical methods were not revalidated as of 10/27/2020 to cover the linearity and accuracy range to meet the current

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FIRM NAME	STREET ADDRESS
Novel Laboratories, Inc. d.b.a LUPIN	400 Campus Dr
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specification in order to demonstrate that the method is linear and accurate for residual API on equipment surfaces.

Product	MAC µg/cm² Current (After 05/27/20)	Validation range per SOP requirement	Validated Range Linearity		Range not covered in current Validation
		Linearity / Accuracy µg/cm² (QL to (b) (4))	Linearity µg/cm²	Accuracy µg/cm²	
Oxycodone/Acetaminophen Tablets ((b) (4))	(b) (4)				
Temazepam Capsules * ((b) (4))					
Trimethobenzamide HCl Capsules * ((b) (4))					
Carbidopa Tablets * ((b) (4))					
Oxycodone HCl Oral Solution* ((b) (4))					

The products marked with an asterisk are still being manufactured after the revision of MAC values without ensuring that the analytical method covers appropriate validated range to cover the MAC concentration.

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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.

Specifically,

SOP No. NL-VA-002.10- 'Cleaning validation and verification Procedure' Section 6.9 states that equipment must be (b) (4) clean (Section 6.9.2), All samples must pass the MAC limits defined in the protocol (Section 6.9.3) and following a minimum of (b) (4) successful Cleaning Validation executions for a cleaning process, the combined data needs to provide a high degree of assurance that the cleaning process will consistently meet the (b) (4) inspections and MAC limits (Section 6.9.4). The procedure further states in Section 6.9.5- If the results from the Cleaning Validation executions meet 6.9.2 and 6.9.3 above, but do not provide this high degree of assurance (6.9.4), additional executions may be necessary, or the cleaning processes may need revising and re-execution of the validation study. Additional executions must be conducted under pre-approved protocol.

The cleaning procedure utilized for non-dedicated manufacturing equipment are not established prior to routine commercial supply. We noted that the firm's current practice is to perform cleaning validation (b) (4) and if the cleaning validation fails to meet the acceptance criteria the firm recleans the equipment till a passing swab result is obtained. The firm further continues the cleaning validation and in multiple instances it was noted that the firm did not have (b) (4) cleaning validation studies and thus failing to meet Section 6.9.5 of the procedure. After the completion of (b) (4) cleaning validation, the firm performs only (b) (4) inspection for the release of cleaned equipment during routine manufacturing operations. Therefore, with no successful minimum (b) (4) cleaning validations, the cleaning verification/ validation study gives no assurance that the cleaning procedure followed is robust enough to thoroughly clean the equipment. Few examples are listed below:

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A. Out (b) (4) Cleaning Validation studies of Hydrocodone Bitartrate and Acetaminophen Tablets 10mg/325mg, the second validation failed to meet the cleaning criteria for the (b) (4) Tablet/Capsules Filler on (b) (4) (Equipment # 0894) (Acetaminophen residue results was (b) (4) µg/swab against the established cleaning limit of NMT (b) (4) µg/swab). Hence OOS investigation was initiated on 10/16/2017 for batch # S700837. The investigation, DEV-17-216 could not assign a definite root cause and extended to manufacturing investigation (CFI-DEV-17-216). Since the (b) (4) line was dedicated to this product during that time, the firm did not conduct manufacturing investigation until 1/8/2020. It was noted that the firm retrospectively initiated manufacturing investigation, CFI-DEV-17-216 on 1/8/2020 and concluded that since (b) (4) filler #0894 was dedicated for (b) (4) of Hydrocodone Bitartrate and Acetaminophen Tablets USP, 10mg/325mg at the time of the OOS result, there is no quality impact on any product or lots. The firm failed to meet the (b) (4) cleaning validation requirements. No other cleaning validation was performed for this product until 8/15/2018. The firm converted the (b) (4) line as non-dedicated from (b) (4) (as per the equipment log 0894) without collecting swab samples prior to the release of the (b) (4) line for other products to ensure that the equipment is free of Acetaminophen residue prior to introducing Temazepam Capsules.

B. The Cleaning Validation studies for the commercial product, Oxycodone and Acetaminophen Tablets, 2.5mg/325mg, 5mg/325mg, 7.5mg/325mg and 10mg/325mg was initiated on 07/17/2019. The following OOS results obtained during the CV studies:

Product: Oxycodone and Acetaminophen Tablets, 2.5mg/325mg, 5mg/325mg, 7.5mg/325mg and 10mg/325mg
Specification revision dates and limit: 07/17/2019 (original) - (b) (4) µg/swab; 10/19/2019 – (b) (4) µg/swab; 01/30/2020 – (b) (4) µg/swab; 05/27/2020 – (b) (4) µg/swab

Total number of Cleaning Verification (CV) studies	Number of times obtained results did not confirm with approved specification	Equipment	Failed CV	Root cause/CAPA

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(b) (4)	1	(b) (4) Tablet Press	OOS-19-051 **2nd CV** (09/27/2019) (b) (4) – (b) (4) µg/swab (b) (4) – µg/swab	Incorrect MAC limits, Specification was updated. No review on updating cleaning procedure.
(b) (4)	1	Tablet/Capsule Filler ((b) (4) slat Filler)	OOS-20-001 **3rd CV** (01/10/2020) (b) (4) – (b) (4) µg/swab	No root cause identified, Specification was updated, Cleaning validation will be further extended.

C. Clean equipment hold time is not supported with scientific rationale. For example, the firm's current practice of "clean equipment hold time" is a default (b) (4). However, the firm does not have data to support the "clean equipment hold time" for building (b) (4) and (b) (4). As per the current cleaning procedure, (b) (4) water is used for the cleaning of equipment including (b) (4) Tank ((b) (4)) and Tablet press. It was noted that on 06/01/2020, the firm reported an Out of Specification result (>(b) (4) cfu/ swab, Spec: NMT (b) (4) cfu/ swab) for total microbial content in the hopper of (b) (4) Tablet press after a major cleaning. The equipment was swabbed on (b) (4) for microbiological analysis after cleaning using (b) (4) water and wiped with (b) (4) (b) (4).

D. On 10/22/20 during our review of excel sheets associated with MAC value calculations we noted difference in surface area in the document provided to us for Oxycodone HCl and the data displayed in the current excel sheet. When asked about the difference the firm management came back stating that inadvertently one of the equipment ((b) (4) was missing in the calculation). The firm had been using non-validated excel sheets for MAC calculation prior to May 2020. This equipment surface area was not included for the Cleaning Validation Study for Oxycodone

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Hydrochloride Tablets, USP 5mg, 10mg, 15mg, 20mg and 30mg, initiated on 10/08/2019. During the review of Cleaning Validation Protocol, document # CVP-01059, it was noted that (b) (4) (b) (4) (b) (4) was not included as shared equipment between Oxycodone Hydrochloride Tablets and Methylphenidate Chewable Tablets, for the calculation utilized for 'total shared surface area' for MAC limit calculation. The impact of this omission is not clear on the MAC values where Methylphenidate Chewable Tablets is considered as the worst-case product.

E. As per SOP # NL-VA-002.8, entitled as "CLEANING VALIDATION AND VERIFICATION STRATEGY" approved on July 25, 2011, revalidation is required when a change has been made to the product, process, procedures for cleaning or equipment. Based on NL-VA-002.9, dated February 03, 2016, changes must be evaluated for their impact on cleaning processes and evaluated for the need to re-validate. The firm introduced Methylphenidate Chewable Tablets in 2015 to the facility. However, an evaluation on MAC limits was never performed prior to the introduction of this product. In May 2020, the firm realized that Methylphenidate Chewable Tablets should be considered as the "worst case product" from a cleanability perspective. The firm updated the MAC limits based on Methylphenidate Chewable Tablets on May 27, 2020. A risk assessment for cross contamination due to the changed specifications was not performed until 10/27/2020. The following table contains previous and current specifications based on the change of worst product:

Product	Previous MAC Limit ((b) (4))	Current MAC Limit ((b) (4))
Hydrocodone Bitartate/Homatropine Methylbromide Tablets, 5mg/1.5mg	(b) (4)	
Methylergonovine Tablets, 0.2mg		
Dexmethylphenidate Hydrochloride Tablets 2.5mg, 5mg and 10mg		
Methylphenidate Hydrochloride Tablets 5mg, 10mg and 20mg		

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Metoclopramide Orally Disintegrating Tablets 5mg and 10mg	(b) (4)
Pentazocine / Naloxone Tablets 50mg/0.5mg	
Phenelzine Sulfate Tablets 15mg	
Quinapril HCl/Hydrochlorothiazide Tablets 10mg/12.5mg	
Tinidazole Tablets (b) (4) mg and 500mg	
Trimethobenzamide HCl Capsules 300mg	

F. Deviation # DEV-SO-858-19-0015 and DEV-SO-858-19-0024 were initiated on 3/19/2019 and 7/30/2019 based on finding of black particles during the manufacturing of Potassium Chloride Oral Solution, USP 20% ((b) (4)). The firm identified that due to the corrosive nature of Potassium Chloride Oral Solution, USP 20% ((b) (4)), the (b) (4) tanks used for manufacturing should be cleaned within (b) (4) . This requirement was implemented for the (b) (4) (b) (4) tanks used for manufacturing. However, a similar tank (Equipment #0976) and transfer lines made of (b) (4) were not included as part of preventive action.

OBSERVATION 7

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically, the firm transferred the product Temazepam Capsules, 15mg and 30mg (batch size (b) (4) Capsules) from building (b) (4) in November 2018. The site manufactured (b) (4) batch as part of site transfer evaluation and concluded that the process could be transferable. Based on the data available at that time, the firm started manufacture of batches in 2019 and 2020. During this period, multiple batches failed analytical testing and were subsequently rejected due to OOS's in (b) (4) and (b) (4) results. One batch was reported as Out of Expectations (OOE) on Assay results. The firm rejected the OOS/OOE batches without identifying the root cause and released the batches those met specifications without evaluating the batches with additional samples testing as of 9/30/2020. The firm

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manufactured (b) (4) batches of Temazepam Capsules, 15mg at building (b) (4) 4 batches were rejected due to OOS and OOE results. In addition, 3 batches of Temazepam Capsules 30mg (batches S901036, S000428 and S000251) were rejected due to OOS due to (b) (4) and weight variation test respectively. In September 2020, the firm identified several areas of improvement which were not considered as part of site transfer. The firm re-validated the product line in September 2020. The batches manufactured from 2019 to 2020 before implementing the process controls and additional sampling, were released and remain in the market.

Temazepam Capsules, 15mg

Sn#	Date of manufacturing	Expiry Date	Batch number	Pkg. batch number	OOS/OOE	Disposition
1.	Nov 2018	Nov 2020	S801155	S801354	No	Release
2.	Dec 2018	Dec 2020	S801385	S900067	No	Release
3.	Jan 2019	Jan 2021	S801387	S900069	No	Release
4.	May 2019	May 2021	S900558	S900752	**OOE - Assay**	**Reject**
5.	May 2019	May 2021	S900559	S900753	No	Release
6.	May 2019	May 2021	S900560	S900754	No	Release
7.	May 2019	May 2021	S900561	S900755	No	Release
8.	Aug 2019	Aug 2021	S901034	S000810	**OOS -(b) (4) (b) (4)**	**Reject**
9.	Nov 2019	Nov 2021	S901559	N/A	**OOS – (b) (4) (b) (4)**	**Reject**
10.	Nov 2019	Nov 2021	S901560	S901676	No	Release
11.	Jan 2020	Jan 2022	S000018	S000099	No	Release
12.	Feb 2020	Feb 2022	S000183	N/A	**OOS – (b) (4) (b) (4)**	**Reject**
13.	Feb 2020	Feb 2022	S000184	S000307	No	Release
14.	Feb 2020	Feb 2022	S000185	S000395	No	Release
15.	Feb 2020	Feb 2022	S000218	S000390	No	Release
16.	Feb 2020	Feb 2022	S000219	S000394	No	Release

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OBSERVATION 8

Buildings used in the manufacturing, processing, packing and holding of a drug product are not maintained in a good state of repair.

Specifically, the firm's manufacturing buildings # (b) (4) and (b) (4) utilized for the manufacturing of drug products are not properly maintained in a good state of repair. The following were observed but not limited to:

A. The firm manufactures potent and non-potent drugs products in building # (b) (4). During the inspectional walkthrough of building # (b) (4), we observed 2 non-classified rooms inside the class (b) (4) area with no entry restrictions in place. For example, Room # (b) (4), labeled as 'utility room' was found with unknown powder residue throughout the wall. Another non-classified room (Room # (b) (4)) utilized for the storage of status labels for equipment and process rooms, and sticky carpets for potent drug manufacturing rooms was found in a state of disrepair. Not all of the ceiling had panels or tiles. The room used for the storage of clean equipment was found located in a non-classified area adjacent to office rooms.

B. In building # (b) (4), marble chips and stones were observed on the floor of utility box behind (b) (4), Equipment # # 0235. This utility box located inside the (b) (4) room, Room # (b) (4) was without a secured access control.

C. In building #(b) (4) (b) (4) water was found on six (out of (b) (4)) (b) (4) air vents located at the (b) (4). The firm's engineering unit could not explain the reason of the localized condensation at the (b) (4). These areas were found (b) (4) to (b) (4) processing rooms.

D. On 9/15/2020, we observed eroding brown colored mass that appeared to be rust; on pipes that carry (b) (4) in building (b) (4) and (b) (4). This (b) (4) comes in direct contract with the product when used for about (b) (4) production equipment.

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E. On 9/30/2020, we observed dark stains on the ceiling and wall of the engineering supply room. Some stains on the ceiling appear to be coming from leaky material. This room connects Building (b) (4) with Building (b) (4) with two doors; each door opens into each building.

F. We observed receiving/shipping doors in the warehouse areas in Building (b) (4) and Building (b) (4) are not sealed completely to prevent entry of the insects and pests into the warehouse used to store raw materials and drug products.

OBSERVATION 9

Separate or defined areas to prevent contamination or mix-ups are deficient regarding the manufacturing and processing operations.

Specifically, controls in place are deficient to prevent contamination of potent drugs into manufacturing and processing areas where other drugs are manufactured.

The firm routinely manufactures about (b) (4) commercial drug products (including two potent drugs i.e. Methylergonovine Maleate Tablets, 0.2 mg and Misoprostol Tablets, 0.1 mg and 0.2 mg) in Buildings (b) (4) and (b) (4) Raw materials, in-process products, and production equipment are frequently moved from one building to the other during (b) (4), and (b) (4). Manufacturing areas, production equipment, and utilities used to manufacture potent drugs are shared with the non-potent drugs. The site does not perform any testing to determine the traces of these potent compounds in the manufacturing areas. Currently there is no data available to ensure that the areas where non-potent drugs are manufactured, processed and packaged are free from potent compounds.

Additionally, the firm uses (b) (4) company-owned trucks to move materials and in-process products from one building to the other. The site does not have any controls in place to clean/sanitize these trucks when used to move potent materials and in-process drugs.

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OBSERVATION 10

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.

Specifically,

A. Firmware instruments (those without a computer attached and not connected to a network) in the QC laboratories do not have sufficient controls to prevent unauthorized access to, change to, or omission of data results. For example, the Density Meter #1295 and Viscometer (DV2T) ID#03 do not have unique logins for (b) (4) analysts and the Density Meter #1295 electronic raw data results can be deleted from the instrument. The Density Meter is used to test Finish Products such as: Methylphenidate Hydrochloride Oral Solution, Oxycodone Hydrochloride Oral Solution, Potassium Chloride Oral Solution USP, GaviLyte-C/G, and GaviLyte-N. Viscometer is used to test Finish Products such as: Potassium Chloride Oral Solution and Voriconazole for Oral Suspension.

B. Shared user IDs and passwords were found being used by employees for (b) (4) Equipment. On 9/24/2020, during the inspectional walkthrough of building (b) (4) we observed a manufacturing operator (b) (6) using another employee's user ID and password while logging into the (b) (4) Equipment (Equipment # (b) (6)). The manufacturing operator stated that the 'user ID' and 'password' were provided by his supervisor when he joined in (b) (6) and he was given permission to use them until a unique 'user ID' and 'password' is provided to him. In building (b) (4) also manufacturing operators use shared password while logging into (b) (4) (b) (4), Equipment # 0235.

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OBSERVATION 11

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

A. There are no procedures to ensure that the Karl Fischer (KF) Moisture Analyzer operates as intended and can accurately assess water content for release testing of the Raw Materials and Finished Products. The firm's SOP NL-QC-039.15 "OPERATION AND CALIBRATION OF THE KARL FISCHER AUTO-TITRATOR AND POTENTIOMETRIC AUTO-TITRATOR" Effective Date 06/09/2020 does not require analysis of a standard that is close to the sample results for an accuracy check. Instead, the firm uses water to conduct the accuracy check with an acceptance specification of (b) (4) However, the QC water content specification for numerous samples is smaller than the (b) (4) range of error for the water accuracy check. In addition, the firm currently only performs (b) (4) accuracy at (b) (4) of the (b) (4) during the calibration of (b) (4) instrument. The intended (b) (4) used is between (b) (4) therefore, the (b) (4) accuracy needs to be performed at different (b) (4) during the instrument calibration for accuracy of the (b) (4).

The water content specifications for following API, Raw Materials, and Finish Products:

Product	Water Content Specification
Potassium Chloride for Oral Solution, USP	NMT (b) (4)
PEG-3350, Sodium Sulfate, Sodium Chloride, Potassium Chloride, Sodium Ascorbate and Ascorbic Acid for Oral Solution (Generic (b) (4))	NMT (b) (4)
Polyethylene Glycol for Oral Solution (GaviLax)	NMT (b) (4)
Quinapril HCl	NMT (b) (4)

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(b) (4)	NMT (b) (4)
Voriconazole, USP	NMT (b) (4)
PEG-3350	NMT (b) (4)
(b) (4)	NMT (b) (4)
(b) (4)	NMT (b) (4)
(b) (4)	NMT (b) (4)
(b) (4)	NMT (b) (4)

B. Your written procedure for calibration of pH meters SOP NL-QC-035.8 "OPERATION, CALIBRATION AND STANDARDIZATION OF pH METERS" Effective Date 03/04/2020, which is used to measure pH in the preparation of mobile phases and diluents, Raw Material release testing, in-process testing, and Finished Product release testing of drug products, is deficient in that:

1. pH probe thermometers are not calibrated as part of the calibration procedure nor are they verified at time of use to ensure that they are reading the correct temperature when the pH is taken. As a result, there is no assurance that the pH readings, which are temperature dependent and automatically adjusted by the instrument, are accurate.

2. During calibration of the pH probe, which is done at least (b) (4), the temperature and offset are not monitored or recorded.

C. Your written procedure for calibration of HPLC SOP NL-QC-031.16 "OPERATION AND CALIBRATION OF HIGH PERFORMANCE LIQUID CHROMATOGRAPHS" Effective Date 02/21/2020, which is used to perform analyses for Assay, (b) (4), (b) (4), Dissolution, and Related Compound of Raw Materials, In-Process, Finish Product, and Stability Samples, is deficient in that the (b) (4) calibration only checks the air temperature of the (b) (4) in one location (exact location not noted in calibration document). There is no

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DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Food and Drug Administration - New Jersey District, 10 Waterview Blvd, 3rd Floor, Parsippany, NJ 07054 973-331-4900 ORAPharm1_responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	09/10/2020-11/05/2020*
	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	STREET ADDRESS: 400 Campus Dr
CITY, STATE, ZIP CODE, COUNTRY: Somerset, NJ 08873-1145	TYPE ESTABLISHMENT INSPECTED: Drug Product Manufacturer

assurance that the (b) (4) is able to maintain (b) (4) across the (b) (4) vial locations within the instrument. The test methods for the following products require a specific temperature for the sample solution prior to injection:

Method #	(b) (4) Temperature	Title
RM-I16561-LC-HCOOH	(b) (4)	(b) (4) - Method of Analysis for (b) (4) (b) (4)
RM-I1656I-LC-HCHO	(b) (4)	(b) (4) - Method of Analysis for (b) (4) (b) (4)
FP-834269-LC-RC	(b) (4)	Azithromycin Tablets, USP– (b) (4)
FP-060-DEG	(b) (4)	(b) (4) and (b) (4) for Oral Solution, USP (b) (4)
FP-358-LC-AS	(b) (4)	Hydrocodone Bitartrate and Acetaminophen Tablets, USP – (b) (4)
FP-358-LC-RC	(b) (4)	Hydrocodone Bitartrate and Acetaminophen Tablets, USP – (b) (4)
FP-123-AS-02	(b) (4)	Temazepam Capsules, USP – (b) (4)
FP-123-DEG-00	(b) (4)	Temazepam Capsules, USP – (b) (4)

OBSERVATION 12

Written procedures are not followed for evaluations done at least (b) (4) and including provisions for a review of complaints, recalls, returned or salvaged drug products, and investigations conducted for each drug product.

Specifically, control procedure for Annual Product Review (SOP No. NL-QA-042.7, Version: 7, Effective Date: 4/26/2018) is not followed to evaluate the products at least annually.

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FIRM NAME	STREET ADDRESS
Novel Laboratories, Inc. d.b.a LUPIN	400 Campus Dr
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Somerset, NJ 08873-1145	Drug Product Manufacturer

The review cycle for each drug product (based on approval of the ANDA) is defined in Annual Product Review SOP. As per this SOP the annual product review report should be completed after (b) (4) of the review cycle. On 9/30/2020, significant deficiencies pertaining to timely completion of annual product review reports were observed as below:

Review Cycle	Total products for review	# of products with delayed review	# of products with review still pending
(b) (4)	(b) (4)	20 ((b) (4)%)	18 ((b) (4)%)
		39 ((b) (4)%)	20 ((b) (4)%)
		36 ((b) (4)%)	0 ((b)%)

As of 9/30/202, the Quality Unit failed to complete the annual review for about (b) (4) products for more than (b) (4) as below:

Product Name	Review Period	Report Due Date	Date Report Approved	Number of Days Delayed
Potassium Chloride ER Tablets 10 mEqK and (b) (4)	01/21/2018 to 01/20/2019	(b) (4)	09/29/2020*	(b) (4)
Phenelzine Tablets, 15mg	12/8/2017 to 12/7/2018		05/29/2019	
Hydrocodone Bitartrate and Homatropine Methylbromide Tablets, 5mg and 1.5mg	4/21/2018 to 4/20/2019		Pending Review	
Tinidazole Tablets, USP 250 mg & 500 mg	4/30/2018 to 4/29/2019		Pending Review	
Methylergonovine Tablets, USP 0.2 mg	5/2/2018 to 5/1/2019		Pending Review	
Temazepam Capsules, USP 15 mg, 7.5mg, 22.5 mg, 30mg	4/21/2018 to 4/20/2019		09/11/2020*	

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CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Somerset, NJ 08873-1145	Drug Product Manufacturer

GaviLyte G	6/1/2018 to 5/31/2019	(b) (4)	09/12/2020*	(b) (4)
GaviLyte C	6/01/2018 to 5/31/2019		09/11/2020*	
Doxycycline capsules, 50, 75, and 100mg	5/28/2018 to 5/27/2019		Pending Review	
Zolpidem Tartrate Sublingual Tablets, 1.75 & 3.5 mg	6/3/2018 to 6/2/2019		Pending Review	
Trimethoprim Tablets, 100mg	06/15/2018 to 6/14/2019		Pending Review	
Orphenadrine ER Tablets, 100mg	06/19/2018 to 06/18/2019		Pending Review	
GaviLyte N	05/27/2018 to 5/26/2019		09/09/2020*	
Voriconazole for Oral Suspension,40mg/5mL	5/31/2018 to 5/30/2019		09/09/2020*	
Flucytosine Capsules 250 mg and 500 mg	07/07/2018 to 07/06/2019		Pending Review	
Oxycodone HCl Oral Solution, 20mg/ml	4/29/2018 to 4/28/2019		07/17/2020	
Misoprostol Tablets, 100 mcg & 200 mcg	7/25/2018 to 7/24/2019		Pending Review	
Nystatin Topical Powder, 100,000 Units/g	7/23/2018 to 7/22/2019		09/29/2020*	
Pentazocine and Naloxone HCl Tablets, 50/0.5 mg CIV	7/11//2018 to 7/10/2019		09/09/2020*	

*Review completed during inspection or after inspection announced

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OBSERVATION 13

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

Specifically,

Your written procedure for laboratory analyst training SOP NL-QC-002.3 "TRAINING OF LABORATORY PERSONNEL" Effective Date 08/11/2014 does not contain a standard training procedure in place for the laboratory analysts for consistent On-the-Job (OJT) training to assure that all analysts receive similar training. Instead, the SOP states that "Assessment of instrument skills based on past experience" and "Extent of Hands-on training necessary will be determined on the basis of (b) (4) (b) (4) " and OJTs for a new employee with previous experiences are skipped. During review of training records for (b) (4) analysts, no OJT records were available. Instead, a Memo was provided for one of the analysts stating that "practical training" had been given on various instruments: Karl Fischer, UV-Vis, Dissolution, HPLC, GC, Density Meter, and Viscometer however, no records of "practical training" were documented and the SOP does not explain what "practical training" consists of.

***DATES OF INSPECTION**

09/10/2020(Thu), 09/11/2020(Fri), 09/14/2020(Mon), 09/15/2020(Tue), 09/16/2020(Wed), 09/17/2020(Thu), 09/18/2020(Fri), 09/24/2020(Thu), 09/25/2020(Fri), 09/28/2020(Mon), 09/29/2020(Tue), 09/30/2020(Wed), 10/01/2020(Thu), 10/06/2020(Tue), 10/07/2020(Wed), 10/08/2020(Thu), 10/20/2020(Tue), 10/21/2020(Wed), 10/22/2020(Thu), 10/23/2020(Fri), 10/30/2020(Fri), 11/05/2020(Thu)

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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."