DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	1/14/2019-1/25/2019*
	FEI NUMBER 3007549629

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Nilesh D. Gupta, Managing Director

FIRM NAME	STREET ADDRESS
Lupin Limited	Unit-2, Plot No. M-2 And M-2-A, Sez, Phase Ii, Misc. Zone, Apparel Park, Dist. Dhar
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Pithampur, Madhya Pradesh, 454775 India	Drug Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

(A) Out of Specification (OOS) Investigation No. OOS/C/18/IN2/SS/012 was initiated on 4th July 2018 for Moxifloxacin Ophthalmic Solution USP 0.5% batch no. H800393 at the 3-month stability time point (RT/Long Term: 25 ± 2 °C and (b) (4) %RH). This batch is an (b) (4) stability batch that represented approximately (b) (4) batches released to the U.S. market. The OOS failure during Related Substances testing was initially categorized as an (b) (4) Impurity at (b) (4) % which exceeded the specification limit of NMT (b) (4) %. During extensive follow-up investigations, the impurity was re-categorized by the R&D group as (b) (4) formed due to (b) (4) component present on the product label containing (b) (4) . Furthermore, the R&D group concluded that product label contributes to the generation of the (b) (4) . A detailed health-hazard assessment for the presence of (b) (4) in the product was not conducted until 17th January 2019 (during the current inspection). The health hazard assessment acknowledged that (b) (4) is a strong irritant to the eyes. Other deficiencies with the investigation include, but are not limited to;

- Failure to re-train analysts who were involved in the purported mis-identification of the impurity

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during the initial testing and subsequent investigation.

- The product labels utilized on the OOS batch (Label lot no. (b) (4)) were also utilized in 3 other commercially released batches (H705563, H800616, and H705562). The firm's decision to analyze retention samples from these three impacted batches and retention samples from all other market batches on a quarterly basis is not scientifically justified. Additionally, the firm deficiently limited the market action (i.e. recall) only to OOS batch H800393 while other impacted batches continued to remain in U.S. market until the current inspection. (b) (4) An updated FAR was filed on 24th January 2019. There is no assurance that product label on the product bottles current in the U.S. market (i.e. approximately (b) (4) batches) are free of (b) (4) Presence of (b) (4) was never historically quantified through adequate testing.
- A CAPA (CAP-IO-153-18-0059) was initiated that included a directive to develop an analytical test method for detecting presence of (b) (4) on the product label. This task was not completed and instead, the CAPA was closed by procuring labels without (b) (4) on the label. An in-house verification test is unavailable to ensure that the new labels would continue to remain free of (b) (4) . In addition, you do not have any record available to substantiate that the label supplier was audited during the investigation.
- The R&D evaluation demonstrated that (b) (4) contributes to the formation of the (b) (4) during 7 days of exposure at RT conditions. The same evaluation reported that (b) (4) was not detected in other batches. The R&D report is silent as to why only the OOS batch was impacted while all other marketed batches with the old label containing (b) (4) are not at risk for the said impurity during the intended shelf life of the product (i.e. (b) (4)).
- The investigation does not record any attempt to procure retention samples representing product labels utilized in marketed batches and no attempt was made to quantify the amount of (b) (4) on the labels.
- As of the current inspection, a formal analytical method re-validation has not been performed to ensure that the current method can adequately detect and quantify the (b) (4)

in the finished product. A limit for (b) (4) has not been established for the finished product. A non-validated test method is currently being used to test the retention samples representing all (b) (4) batches on the market as part of the on-going analysis.

- Your CAPA to evaluate retention samples through a protocol study every 3 months is not scientifically sound. There is no assurance that the label lots used in the marketed batches uniformly contained the same level of (b) (4) (and (b) (4)).
- As a corrective action for the OOS Investigation, the product labels were changed from labels containing (b) (4) (material code: (b) (4)) to labels containing no (b) (4) (material code: (b) (4)). The current stability shelf life of the product of (b) (4) was established utilizing the old product labels with material code (b) (4). Approximately (b) batches were released to the U.S. market containing the revised product label with material code (b) (4). A stability study for the product with the new labels was not conducted and hence, the current shelf life of (b) (4) for the product (with the new product labels) is not substantiated by any stability data.

(B) Out of Specification (OOS) Investigation No. OOS/C/18/IN2/SS/016 for (b) (4) Capsules USP (b) (4) mg was initiated on 23rd July 2018 when OOS dissolution results were obtained for batch # (b) (4) at the 3-month stability (Long Term: 25 ± 2 °C and 60 ± 5 %RH) time point. The OOS results obtained were as follows:

Time Points	Minimum (%)	Maximum (%)	Average (%)	Specification
1 hour	(b) (4)			NMT (b) (4) %
2 hours				(b) (4) to (b) (4) %
4 hours				(b) (4) to (b) (4) %
8 hours				NLT (b) (4) %

The resulting investigation was completed with an "invalid" decision on 18th September 2018. Independent review of the investigation by third party consultants disagreed with the conclusions drawn

from the investigation during their 1st and 2nd review. The root cause identified as due to "addition of (b) (4) quantity of (b) (4) solution and skipping the addition of (b) (4) solution during (b) (4) dilution of samples at initial OOS analysis" continue to remain unsubstantiated. This root cause is not conclusively proven in the resulting OOS investigation. The most recent update to the investigation is currently pending review by third party consultants. Additionally, approximately 6 months have lapsed since OOS investigation was initiated. The firm has no procedural controls to ensure that OOS investigations pertaining to stability samples are investigated and completed in a timely manner. (b) (4) Capsules, (b) (4) mg with batch number (b) (4) is currently in the U.S. market with an expiration date of February 2020.

(C) Out of Specification (OOS) Investigation No. OOS/C/18/IN2/SS/018 for (b) (4) Tablets (b) (4) mg, (b) (4) mg and (b) (4) mg was initiated on 26th September 2018 when the Assay results from batches (b) (4), (b) (4), and (b) (4) at 3-month stability testing (Long Term: 25 ± 2 °C and 60 ± 5 %RH) yielded OOS Assay results for the (b) (4) and (b) (4) components. The resulting investigation attributed the root cause to a malfunctioning sonicator. During hypothesis studies, batch (b) (4) was selected for a study where the sample stock was prepared without sonication to prove malfunctioning sonicator yielded OOS results. However, review of the hypothesis study results for batch (b) (4) indicate that "no sonication study" (purportedly the worst case) yielded results as follows:

	(b) (4)	(b) (4)	(b) (4)
Initial OOS Results – Assay	(b) (4) %	(b) (4) %	(b) (4) %
Hypothesis study (no sonication) – Assay	(b) (4) %	(b) (4) %	(b) (4) %
Absolute % difference in Assay from initial	0.8%	25.4%	14%

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OOS results			

The investigation is silent as to why the no sonication hypothesis study (i.e. worst case) resulted in Assay values that were approximately 25.4% and 14% higher (absolute difference) for the (b) (4) and (b) (4) components, respectively. The investigation report indicates that the sonicator was functional during the analysis but purportedly not at optimum working conditions. A sonicator performance verification on 27th September 2018 did not indicate that the sonicator was completely in a non-working status. As such, the root cause due to extraction issue as a result of a malfunctioning sonicator is not conclusively proven during the investigation. These three batches continue to remain in the U.S. market as of the current inspection. The three batches were PV batches from an alternate API vendor for (b) (4).

(D) OOS Investigation No. OOS/C/17/IN2/FP/013 was initiated on 28th July 2017 for (b) (4) Capsules USP (b) mg/(b) (4) mg where batch (b) (4) was rejected due to Assay failure at (b) (4) % for (b) (4) against a specification limit of (b) (4) to (b) (4) %. A 2nd batch in the campaign ((b) (4)) was flagged as an Out of Trend with an Acceptance Value of (b) (4) (for Content Uniformity). The following deficiencies were noted with regards to this investigation:

- (b) (4) sampling during the investigation for batch (b) (4) indicated failing results. However, no (b) (4) sampling of the 2nd batch ((b) (4)) in the campaign was considered.
- The 2nd batch ((b) (4)) in the campaign was released and distributed to the U.S. market on 14th August 2017. Long term impact (if any) on the batch was not evaluated by placing the batch on stability.
- A root cause of the Assay failure was never identified. Nevertheless, an evaluation of the product's validated status was not considered.

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Manufacturing investigation (Phase II) indicated that there was no difference in the manufacturing processes among batches (b) (4) and (b) (4). There is no assurance that the released 2nd batch would consistently remain within its specification limits during the intended shelf life of (b) (4). Batch (b) (4) is currently in the U.S. market with an expiration date of (b) (4)

(E) Your firm has invalidated several Out-of-Specification (OOS) results obtained during the testing of environmental monitoring as summarized below: You attributed several of them to human error which raises concerns about the ability of your laboratory personnel to properly conduct the required analytical testing. For example;

- OOS investigation, EMO/OOS/18-001 was initiated on 04/15/2018 for routine air monitoring sampling activity (no filling) where the result for Location #(b) (4) found exceeding the acceptance limits (b) (4) CFU (Action/Level Limit (b) (4) CFU). Your firm attributed the root cause as human error through a deficient investigation and interview where the sampler lid might have not been properly sanitized before sampling in (b) (4) ((b) (4)). When interviewing the Analyst (Officer Micro) during the inspection on 01/21/2019 using the same questions raised in the investigation report, his response did not corroborate what is stated in the OOS investigation report conducted by your firm. For example, in the OOS report he said for Question 6 that "I have taken plates from PPM stagining and loaded at (b) (4) trolley. After loading, air sampling was performed as per sequence mentioned below: (b) (4) again entered in Aseptic area and performed settle plate exposer following the sequence as above in each step, I have sanitized the hand while (b) (4)", but in person on 01/21/2019 he said "Firstly, sequence of (b) (4), it mentions in our SOP (QC2-128-13)." Your firm invalidated the failing result through your interview process.

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OBSERVATION 2

Written records of investigation of a drug complaint do not include the findings of the investigation and the follow-up.

Specifically, your complaint investigations are deficient. You have received several repeated market complaints for (b) (4) Tablets USP ((b) (4) mg/(b) (4) mg, (b) (4) mg/(b) (4) mg, and (b) (4) mg/(b) (4) mg) and (b) (4) Tablets (b) (4) mg) since 2011/2012 for black spots, blackish greyish spots, and "mold" on the marketed finished products in the U.S.A. In all resulting investigations, you concluded the root cause as the result of oil (or food grade lubricant used during the compression process) mixed with fine product dust forming lumps and/or black spots, blackish greyish spots. Despite the number of investigations summarized below, none of the investigations conclusively provides any evidence that the lubricating oil when adhered to the finished product results in finished products with black spots or molded tablets. Additionally, a detailed health hazard evaluation (HHE) was not performed until 24th January 2019 (during the current inspection). However, the HHE fails to provide assurance that the finished products contaminated with potentially denatured lubricant oil are safe and effective for the consumers.

The following complaints have been recorded and investigated for the following products since commercialization:

Product	Complaints
(b) (4) Tablets USP (mg/ mg, mg/ mg, and mg/ mg)	42 (since 2012)
Tablets mg)	17 (since 2011)

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OBSERVATION 3

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

Specifically,

There is a lack of oversight by firm management, especially the QC, QA, Warehousing, Production, and IT departments, to ensure employees are performing their required job functions as specified in your firm 's SOPs. During the inspection, we observed several instances where it appeared that top management, general managers, supervisors, specialists, and personnel engaged in the activities related to the manufacture, testing, holding and review of procedures, documents, methods, and data could not autonomously answer questions related to their day to day job functions or activities in which they routinely participated or would hastily provide an answer without consideration of the question which was asked. Many employees, including the QA, QC, Warehousing, Production, and Validation Managers, would directly read the procedure from the document without being able to autonomously comment on activities and operations in which they are described to be familiar with and knowledgeable of. Additionally, firm personnel would provide data and evidence which did not support the claims that could provide answers to specific questions asked by the investigators. For example:

A. Your firm's Manager of IT, Deputy General Manager of Engineering, Sr. Executive IT, Manager Validation/QA provided us with the following (b) (4) and (b) (4) building management systems (BMS) validation documents for the (b) (4) building and (b) (4) building (Sterile) in which they participated in the validation studies and/or is part of their duties. However, when we asked them why they did not follow the established/approved Validation Master Plan (VMP)/ Protocol for the validation such as issuing a system release certificate and writing a validation summary report as part of the validation deliverables. They could not answer and provide a justification.

B. Document #VMP-003-INP-00 (Validation Master Plan Manufacturing Software System at Lupin Limited, Pithampur) 08/24/2018 effective date.

C. On 01/21/2019 during the walkthrough of the Analytical QC Laboratory, we asked the Deputy General Manager (b) (4) -Quality Control who oversees the QC Laboratories as part of his duties if he maintains a logbook for every equipment in the lab. He stated yes they do. We then asked him to provide us with the logbook for the ATAGO Refractometer RX-7000CX (Asset #RM-03). He could not provide us with the request as he was notified by one of his staff that they are currently using Electronic Logbook (eLog) System V 1.0.0. We asked him if the equipment is connected to a data acquisition system. He could not provide us with an answer. We then asked him how the information captured from the equipment is documented into the e-log system. He could not answer the question. Then, both the President of Technical Operations and the Managing Director asked him the same question in a different way and local language. Still, he could not answer the question. We asked him to show us how the review of entries in the e-log is performed and if he could show us a document in the e-log system where reviews have been performed. He tried to log in and could not access the system. He finally stated he has no access to e-log. It took approximately 45 minutes for him to answer these questions. During the review of his training records, it revealed that he has been trained on the SOP and is assigned a "Manager" role in the system. In addition, he is overdue on the following SOPs:

- CQA-106 (Production Planning and Tracking of Batches at Different Manufacturing Stages)
- CQA-110 (Reduced Testing, Rev.00, 10/19/18 effective date)
- QC2-027 (Operation of (b) (4) Process, Rev. 01, 03/12/2018)
- QC2-278 (Standard Management in SAP, Rev. 00, 10/23/2018)

D. On 01/21/2019 during the walkthrough of the Analytical QC Laboratory, we asked the Manager of QC if he could explain the sample management process (receiving of samples through issuing

of samples to Analysts). I asked him at least 3 times in different manner and rephrased the question. He could not fully answer. Then, the Managing Director, President of Technical Operations, and GM Quality asked in different manner including local language. It took him nearly 40 minutes to explain the process. He has been trained on SOP # SOP-UNIT2-QC2-178-07 (Sample Management of QC Sample Ver. 07) on 01/25/2018.

E. On 01/21/2019 during the walkthrough of the Analytical QC Laboratory, we asked Executive QC if he could tell us the dates when column #L19000563 was received in QC and issued for use. This column is used for (b) (4) Solution (b) (4) %. He could not provide us with the requested information, which is part of his duties to account for incoming laboratory equipment. It took nearly half an hour with assistance of other personnel to access the SAP system in order to provide us with the information. We then asked him if he could tell us if the specific column has been used for testing (b) (4) Solution (b) (4) %. He stated no. We then asked the Sr. Executive QC if he could tell us if the column had been used. He provided us with the printout from the e-column usage logbook showing it had been used for (b) (4) injections.

F. On 01/23/2019, we asked the Manager of QC and the Officer IT if they could access the Electronic Logbook (eLog) System V 1.0.0 to show us the user group's roles and access level. The eLog is the data acquisition software used by the firm to capture activities. They could not perform the task which is part of their duties and warranted a conference call with your CQA personnel and the vendor of the software.

G. On 01/24/2019, we asked the Sr. GM Corporate IT regarding the provided list of "Administrators" for user creation form/ e-Log Software System Administration User List, how users (Administrators and Vendors) are added, changed, and removed. He stated that he is knowledgeable of the software and could not fully explain the process when he came into the conference room. For example, we observed a username in this format (firstnamelastname1) and

when asked him how it is being created and why. He stated that it is being done when the global directory already has a user with similar name. We asked him to show us where that process is described in their established SOPs. He stated it is not described. I requested his training records and it revealed that the firm does not maintain training records for his position.

H. On 01/24/2019, we asked your Sr. GM Corporate IT to provide us with the user creation form for one of the firm's administrators. Your Sr. GM Corporate IT and the Manager Site IT stated the requested form could not be found. We then asked him to show us in the eLog software system when the "Administrator" (b) (6) was removed from the system. He called on your Officer, Site IT to show us (which is part of his job functions and has been trained on the process) and It took him approximately 13 minutes (12:50pm-1:03pm) to demonstrate when the vendor/administrator was removed from the system although his training records revealed that he was trained on the SOP #QC2-229-00 (User Management and Master Data Creation for Electronic Usage Log System) on 07/20/2015 and Ver. 01 on 10/03/2015.

I. Your firm does not maintain training records for the GM CQA position.

J. On 01/16/2019, we asked an apprentice from Quality Control – Microbiology how he collects (b) (4) samples for routine analysis. He identified himself during the interview that he was responsible for collection of (b) (4) samples for routine analysis from the (b) (4) production area. He was unable to answer a Yes/No question (pertaining to the methodology of (b) (4) sample collection from (b) (4) production block) when asked repeatedly in English and in the local vernacular language.

OBSERVATION 4

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

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Specifically,

The Electronic Logbook (eLog) System V1.0.0 is used for Instrument, Equipment, Area Operation and Cleaning usage log for Production, Warehouse, and Quality Control departments of Lupin Limited. The eLog is not directly connected to respective equipment.

A. Your firm including your Sr. GM Corporate IT cannot assure us that access to the system is adequately controlled. There is no guidance provided for Vendor Administrator to eLog. On 01/23/2019, your Officer Site IT stated during the interview process that all (b) (4) employees he selected from the eLog system directory (as part of his job functions) are active employees of Lupin Limited. When asked for supporting documentation of the Lupin ""Administrators" and the vendor "Administrator" to corroborate histhe statement, he stated on 01/24/2019 that only 10 of the (b) (4) two individuals of the (b) (4) (2/(b) (4)) (assigned as Administrators) previously reported are as Lupin Limited's personnel are in fact vendors. The firm could not distinguish between vendor administrator and Lupin Site IT Administrator from eLog system. (Administrators).

B. SOP #QC2-229-01 (*User Management and Master Data Creation for Electronic Usage Log System*, 10/16/15 effective date) and version 00 do not define the following roles for the system (Administrator, QA Manger, and Vendor). In addition, most the practices performed by your users and described by your Corporate IT CQA and Site IT personnel are not defined in the SOP. For example, raising "Incident Ticket" when users are being added is not described in the SOP.

C. The review of the audit trail for Electronic Logbook (eLog) System Version 1.0.0. in Unit 2 revealed that the "Reviewer" role has more (full) rights to the system than the "Administrator" and the system is managed by QC.

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OBSERVATION 5

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. The qualification of your firm's (b) (4) Systems instrument Software version 07.01 lacks data to fully support it was validated following the re-installation in December 2018. The (b) (4) Systems ((b) (4)) is used to perform microbial identification in the Microbiology Laboratory. The existing software file was corrupted and the analyst and reviewer were unable to access the software. Per your vendor 's recommendation, Software 07.01 needed to be re-installed for (b) (4) (microbial identification system). You initiated change control #CCP-IO-155-18-0040 on 11/21/2018 to revalidate the software and stated that (b) (4) system shall be used for routine identification only after firm successful performed IQ, OQ and PQ of the re-installed software version 07.01. You did not initiate a validation protocol including the deliverables for the revalidation and did not issue a summary report to summarize whether the system has been validated, complied, and released for use. Since re-installation this equipment has been used approximately (b) times for (b) (4) environmental samples where US marketed products are manufactured ((b) (4) and (b) (4) Blocks).

B. Your firm utilizes Electronic Logbook (eLog) System Version 1.0.0. in Unit 2 facility to document the all activities including results of analytical data for laboratory equipment and production. Your firm processed Change Control #CCP-IO-135-14-0009 to implement Logbook System Version 1.0.0. in Unit 2. Your firm did not execute a validation protocol including a validation summary report for the software Electronic Logbook System Version 1.0.0.

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OBSERVATION 6

Established laboratory control mechanisms are not documented at the time of performance.

Specifically,

A. There is no defined process regarding the issuance of Certificate of Analyses (COAs) for (b) (4) analyses conducted in the QC Laboratories. Per your VP of CQA, the QC Laboratories issue COAs for (b) (4) testing for only regulatory submission. However, this statement is not described in SOP #QC2-067-04 (*Certificate of Analysis, 01/16/18 effective date*). In addition, we observed a folder labeled "12.12.18" located on the Microbiology Laboratory's PC drive filled with data was being shared among the laboratory personnel. The approval dates on the COAs do not match the approval date on the test data sheet and date of release. The tested (b) (4) reflected on the COAs was then utilized to manufacture the following US marketed products

Sr.No	(b) (4) A.R Number	Date of Sampling	Product Name	Batch number
01	140000258706 ((b) (4))	(b) (4)	(b) (4) Tablets (b) (4) mg (b) (4) Tablets USP (b) (4) mg (b) (4) Tablets USP (b) (4) mg (b) (4) Tablets USP (b) (4) mg	(b) (4)

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EMPLOYEE(S) SIGNATURE
Jogy George, Investigator
Yvins Dezan, Generic Drug User Fee Amendments (GDUFA)

X Jogy George Investigator Signed By 2001622444 Date Signed 01-25-2019 17 21 03

DATE ISSUED
1/25/2019

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	1/14/2019-1/25/2019* FEI NUMBER 3007549629

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Nilesh D. Gupta, Managing Director

FIRM NAME	STREET ADDRESS
Lupin Limited	Unit-2, Plot No. M-2 And M-2-A, Sez, Phase Ii, Misc. Zone, Apparel Park, Dist. Dhar
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Pithampur, Madhya Pradesh, 454775 India	Drug Manufacturer

Sr.No	(b) (4) A.R Number	Date of Sampling	Product Name	Batch number
			(b) (4) Tablets USP (b) (4) mg (b) (4) Tablets USP (b) (4) mg (b) (4) Tablets USP (b) (4) mg (b) (4) tablets USP (b) (4)	(b) (4)
02	140000260809 ((b) (4))	(b) (4)	(b) (4) USP (b) (4) (b) (4) mg	
03	140000278118 ((b) (4))	(b) (4)	(b) (4) USP (b) (4) (b) (4) mg (b) (4) Tablets USP (b) (4) mg (b) (4) for (b) (4) Tablets USP (b) (4) mg & (b) (4) mg (b) (4) Tablets USP (b) (4) mg (b) (4) Tables USP (b) (4) Mg ((b) (4))	
04	140000278877	(b) (4)	(b) (4) Tablets USP	

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CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Pithampur, Madhya Pradesh, 454775 India	Drug Manufacturer

Sr.No	(b) (4) A.R Number	Date of Sampling	Product Name	Batch number
	(b) (4))		(b) (4) mg (b) (4) for (b) (4) Tablets USP (b) (4) mg & (b) (4) mg (b) (4) Tablets USP (b) (4) mg	(b) (4)
05	140000279089 (b) (4))	(b) (4)	(b) (4) USP (b) (4) mg (b) (4) Tablets USP (b) (4) mg (b) (4) for (b) (4) Tablets USP (b) (4) mg & (b) (4) mg (b) (4) Tablets USP (b) (4) mg (b) (4) Tablets USP (b) (4) mg	
06	140000279362 (b) (4))	(b) (4)	(b) (4) for (b) (4) Tablets USP (b) (4) mg & (b) (4) mg (b) (4) Tablets USP (b) (4) mg (b) (4) USP (b) (4) mg (b) (4) Tablets USP (b) (4) mg	

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CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Pithampur, Madhya Pradesh, 454775 India	Drug Manufacturer

Sr.No	(b) (4) A.R Number	Date of Sampling	Product Name	Batch number
			(b) (4) Tablets USP (b) (4) mg (b) (4) Tablets USP (b) (4) mg	(b) (4)
07	140000279747 ((b) (4))	(b) (4)	(b) (4) (b) (4) Tablets USP (b) (4) mg (b) (4) Tablets USP (b) (4) mg (b) (4) TAB (b) (4) mg (b) (4) TAB (b) (4) mg	
08	140000280917 ((b) (4))	(b) (4)	(b) (4) USP (b) (4) (b) (4) mg	
09	140000280918 ((b) (4))	(b) (4)	(b) (4) USP (b) (4) (b) (4) mg (b) (4) Capsules (b) (4) g	

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CITY, STATE, ZIP CODE, COUNTRY Pithampur, Madhya Pradesh, 454775 India	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer

Sr.No	(b) (4) A.R Number	Date of Sampling	Product Name	Batch number
			(b) (4) Tablets USP (b) (4) mg	(b) (4)
			(b) (4) TABLETS USP (b) (4) mg	
			(b) (4) Tablets USP (b) (4) mg	
			(b) (4) Tablets USP (b) (4) mg	
10	140000281052 ((b) (4))	(b) (4)	(b) (4) Capsule (b) (4) g	
			(b) (4) Tablets USP (b) (4) mg	
			(b) (4) USP (b) (4) mg	
			(b) (4) Tablets USP (b) (4) mg	
11	140000281052 copy ((b) (4))	(b) (4)	(b) (4) Capsules (b) (4) g	
			(b) (4) Tablets USP (b) (4) mg	
			(b) (4) USP (b) (4) mg	
			(b) (4) Tablets	

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CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Pithampur, Madhya Pradesh, 454775 India	Drug Manufacturer

Sr.No	(b) (4) A.R Number	Date of Sampling	Product Name	Batch number
			USP (b) (4) mg	
12	140000282432 ((b) (4))	(b) (4)	(b) (4) USP (b) (4) / (b) (4) mg (b) (4) USP (b) (4) / (b) (4) mg (b) (4) Tab USP (b) (4) / (b) (4) mg US((b) (4)) (b) (4) Tablets USP (b) (4) mg	(b) (4)
13	140000284118 ((b) (4))	(b) (4)	(b) (4) USP (b) (4) / (b) (4) mg (b) (4) USP (b) (4) / (b) (4) mg (b) (4) Tablets USP (b) (4) mg (b) (4) Tab USP (b) (4) / (b) (4) mg	
14	Screen shot (140000281052) ((b) (4))	(b) (4)	(b) (4) Capsules (b) (4) g (b) (4) Tablets USP (b) (4) mg (b) (4) USP (b) (4) / (b) (4) mg (b) (4) Tablets	

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Lupin Limited	Unit-2, Plot No. M-2 And M-2-A, Sez, Phase Ii, Misc. Zone, Apparel Park, Dist. Dhar
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Pithampur, Madhya Pradesh, 454775 India	Drug Manufacturer

Sr.No	(b) (4)	A.R Number	Date of Sampling	Product Name	Batch number
				USP (b) (4) mg	

B. There is no documented log for the equipment maintained by your firm when (b) (4) (ID #QC2-PB-02) is cleaned. This (b) (4) is used for transferring environmental media plates from the Microbiology Lab to the aseptic facility ((b) (4)) and from the facility to the Microbiology Laboratory. There is a label on the (b) (4) that states, "Surface sanitize the articles using a (b) (4) unloading." We observed your firm recorded several OOS investigations for environmental monitoring including EMO/OOS/18-001 where the result for Location #(b) (4) was found exceeding the acceptance limits (b) (4) CFU (Action/Level Limit (b) (4) CFU) related to (b) (4) within the (b) (4) Block.

***DATES OF INSPECTION**
1/14/2019(Mon), 1/15/2019(Tue), 1/16/2019(Wed), 1/17/2019(Thu), 1/18/2019(Fri), 1/21/2019(Mon), 1/22/2019(Tue), 1/23/2019(Wed), 1/24/2019(Thu), 1/25/2019(Fri)

X Yvins Dezan
Generic Drug User Fee Amendments (GDUFA)
Signed By 2001997410
Date Signed 01-25-2019 17 24 02

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