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	5/13/2024-5/24/2024*
	FEI NUMBER 3005587313

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mr. Uday Kasbekar, Head of (b) (4) Site Operations

FIRM NAME	STREET ADDRESS
Mylan Laboratories Limited	F - 4 Fdf - 1, Pune-Nashik Road; And F - 12
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Sinnar, Maharashtra, 422113 India	Finished 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

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

Specifically,

A. Addendums performed for closed investigations by your firm as a result of your most recent Global Quality Program Audit performed by Global Operations Audit (GAO) personnel in (b) (4) and Global Quality Investigations Team (GQI) retrospective review of closed investigation assessment reports for (b) (4) and (b) (4) are not always documented in your firm's Quality System, specifically documentation of these corrections/addendums with official Corrective Action/Preventive Action (CAPA's) per procedure SOP-000464284, titled "Corrective/Preventive Action (CAPAs) with Effectiveness Check". Specifically,

1. Per our request, your firm provided a list of all CAPA's initiated in response to your (b) (4) (b) (4) Global Quality Audit, which per your firm included CAPA's for all deficiencies identified by your GAO personnel. However, during our review of LIR 3046329, Assay test of (b) (4) Tablets USP (b) (4) mg at 2M accelerated stability analysis, dated 01/20/2023, we observed that your firm had performed an addendum to the investigation in TrackWise software with respect to the root cause analysis "to address the details against observation of Global Operations Audit (GOA) inspection". We observed similar deficiencies for addendums and re-opening of investigations due to audit deficiencies observed by GAO, which per your firm involved

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Arsen Karapetyan, Investigator - Dedicated Drug Cadre Wayne D Mcgrath, Investigator X Arsen Karapetyan Investigator - Dedicated Drug Cadre Signed By: Arsen Karapetyan -S Date Signed: 05-24-2024 02:58:15	5/24/2024

investigations (OOS, OOC, QIA, Invalid) PR ID 3321461, PR ID 3309246, PR ID 3209736, PR ID 2954285, PR ID 2437175, PR ID 2440026, PR ID 2370555, and PR ID 2784330.

2. During our review of Global Quality Investigations Team (GQI) retrospective review of closed laboratory and manufacturing investigations assessment reports for (b) (4) and (b) (4) we observed the following:

-For (b) (4) and (b) (4) assessment reports, GQI reviewed at least 180 laboratory (LIR) and 125 manufacturing (MIR) investigations for (b) (4) with comments such as, but not limited to, "no root cause determined", "inadequate CAPA", "no CAPA initiated", and "Additional supporting information / data required". A majority of the approximate 616 LIR's and MIR's reviewed from (b) (4) were observed to have such comments from GQI with respect to inadequate root cause analysis, lack of scientific rational and supporting evidence, inadequate impact assessments, inadequate corrective actions.

-For Investigations Retrospective Review Assessment Report, Review Period (b) (4) GQI's review of 181 LIR and 130 MIR investigations, resulted in thirteen (13) investigation records (3 LIR, 10 MIR) which, after your firm's review of GQI's comments, required an addendum by your firm. There is no adequate justification for choosing to perform 13 investigation addendums, where majority of investigations reviewed by GQI appeared to have deficiencies, as stated in above paragraph. Additionally, these addendums to investigation reports were not documented in your Quality system, with documentation of these activities with appropriate CAPA's.

-For Investigations Retrospective Review Assessment Report, Review Period (b) (4) GQI's review of 180 LIR and 125 MIR investigations, resulted in thirty-nine (39) investigation records (25 LIR, 14 MIR) which, after your firm's review of GQI comments, required an addendum or to be re-opened. There is no adequate justification for choosing to perform 39

investigation addendums/re-opening, where majority of investigations reviewed by GQI appeared to have deficiencies. Additionally, these addendums to investigation reports were not documented in your Quality system, with documentation of these activities with appropriate CAPA's.

-No trending studies and assessments have been performed by your firm or Global to determine what type of deficiencies (i.e. root cause/CAPA/impact assessment/scientific rationale) were observed within the (b) (4) and (b) (4) why addendums from (b) (4) to (b) (4) went from 13 to 39 (a 3x increase in deficient investigations) when a similar number of investigations (181 vs. 180) were reviewed by GQI, and whether the sampling plan to select the number of investigations to review for GQI is adequate with the 3x increase observed from (b) (4) to (b) (4)

-Finally, the retrospective reviews did not appear to be comprehensive/adequate, in that, an evaluation with respect to impact on product quality, safety, efficacy, or purity of commercially distributed products was not performed after performing addendums and the review did not extend to additional product batches listed on LIR's not chosen due to sampling plan, which may have had similar inadequate OOS investigation deficiencies as observed in the 13 addendums performed (b) (4) and 38 addendums performed (b) (4)

B. The Quality Unit lacks adequate control over the issuance of controlled laboratory worksheets, purported to be controlled under your procedures SOP-000566130, titled "Document Control" and SOP-000487919, titled "Procedure for Operation of Sample Work Flow Module in LIMS Application". During our walkthrough of your laboratory facility, we observed that, worksheets generated on your Caliber LIMS software are not controlled. For Example, your firm generated test worksheet for (b) (4) raw material through your Calibers LIMS software which was sent to your printer. After printing this worksheet with "Copy No.:1" label, your firms laboratory analyst was observed to have the capability to scan this document to another QC personnel via the printer, which was performed, who was able to print a second duplicate copy of

this "Copy No.:1" labeled worksheet.

OBSERVATION 2

Written records of investigations into unexplained discrepancies and the failure of a batch or any of its components to meet specifications do not always include the conclusions and follow-up.

Specifically,

A. During our inspection, we observed that investigations initiated and performed by your Quality Unit in response to complaints, out-of-specification, out of trend, and atypical results are not always performed within your firm's Quality System. Specifically, draft investigations are emailed to your firms Globally Quality Investigation (GQI) team, after which GQI reviews the draft investigation, with track changes/comments, and sends the attached draft investigation with suggested changes back to your firm's quality team via email. Per your firm, for the period from January 2020 to 2024 (current inspection) your Information Technology head, working alongside Global, was only able to retrieve email attachments for approximately 52 CQN investigations out of a total 229 CQN's performed, with the remaining CQN's not present in the server. The reviews performed by GQI were observed to have resulted in changes to investigations performed at your firm. Subsequently, these changes were not documented in your validated TrackWise software, used for initiating, documenting, and closure of investigations. For Example, but not limited to:

1. For LIR 3378419, dated 01/09/2024 (OOT results in Organic Impurity for (b) (4) Tablets (b) (4) mg 18 M Long Term Stability station, batch numbers (b) (4) a Critical Qualification Notification (CQN) 3386865, dated 01/18/2024 was initiated by your firm to prompt the review of the LIR by GQI. GQI's review resulted in material changes in the investigation, including root cause classification change in Trackwise, additional information regarding impurity observed in accelerated studies and forced degradation, and addition of

details regarding impact on all other batches kept on stability. The email communications between your firm and GQI with all comments and suggestions, some of which were not accepted by your firm, was not documented in your Quality System.

Additionally, our review of this LIR during the inspection found three additional LIR's (PR ID 2957424, dated 11/07/2022; PR ID 2187810, dated 05/27/2020; and PR ID 2030511, dated 11/18/2019), where OOT results for organic impurity were observed for various stability stations for (b) (4) Tablets. Investigations for these LIR's appears to have been insufficient, as the firm recently initiated CAPA PR ID 3378419, dated 02/07/2024 to perform an additional method validation for newly identified impurity at RRT (b) (4)

2. For LIR 3448982, dated 03/22/2024 (OOS result in Assay test for (b) (4) Capsules at expiry stability station, Batch numbers (b) (4) CQN 3450221, dated 03/23/2024 was initiated by your firm to prompt the review of the LIR by GQI. GQI's review resulted in material changes in the investigation, including, but not limited to, root cause analysis (sonicated sample vs. not sonicated) and CAPA's performed. The email communications between your firm and GQI with all comments and suggestions was not documented in your Quality System.

   Additionally, our review of this LIR found that your firm failed to mention that CAPA PR ID 3168080, dated 05/25/2023, had been initiated and recently completed to evaluate the assay analytical method of (b) (4) capsules for better extractability of the API, which is a significant development in the test method. This CAPA was initiated approximately 10 months prior to the LIR.

3. For LIR 3219077, dated 07/17/2023 (OOS and Atypical results observed in Organic Impurities test of (b) (4) Tablets (b) (4) mg at 18 Month Long Term stability station, batch number (b) (4) CQN 3220907, dated 07/18/2023 was initiated by your firm to prompt the review of the LIR by GQI. GQI's review resulted in material changes in the investigation, which

included the addition of "moisture ingress" due to improper sealing of the blister pack. The email communications between your firm and GQI with all comments and suggestions was not documented in your Quality System.

4. For Market Complaint 3478065, dated 04/20/2024, regarding foreign tablet found with (b) (4) Tablets, batch number (b) (4) CQN 3479068, dated 04/23/2024 was initiated by your firm to prompt the review of the complaint by GQI. GQI's comments and suggestions resulted in your firm adding additional supporting information to the investigation. The email communications between your firm and GQI with all comments and suggestions was not documented in your Quality System.

5. For (b) (4) Supply Form report PR ID 3194291, dated 06/20/2023, regarding loose material identified in product bottle during repackaging operations (b) (4) for drug product (b) (4) mg, CQN 3271658, dated 09/12/2023 was initiated by your firm to prompt the review of the investigation by GQI. GQI's comments and suggestions resulted in your firm adding additional supporting information to the investigation. The email communications between your firm and GQI with all comments and suggestions was not documented in your Quality System.

6. Affiliate Investigation Report 3194404, dated 06/16/2023, was initiated by your firm for complaint regarding contamination with black flakes for drug product (b) (4) (b) (4) Tablets, batch number (b) (4) Your firm initiated CQN 3195449, dated 06/21/2023 to prompt the review of the investigation by GQI. Prior to September 2023, GQI used "FORM-000809069, Global Quality Investigation Review Form" to provided feedback/comments with respect to review of CQN investigations. Our review of this form found GQI's investigation resulting in "No comments or recommended actions", however, during our review of email communications between your firm and GQI we observed a draft investigation with too numerous to list comments provided by GQI, which resulted in your firm

changing your root cause analysis from "though the possibility of a broken/leaking desiccant being introduced in bottle pack from Nashik site cannot be completely ruled out" (initial report before GQI review) to "possibility that broken/leaking desiccant being introduced in the bottle pack during packing at Mylan Nashik" (written on draft investigation after GQI review) to "Due to procedural controls, the possibility of broken/leaking desiccant being introduced in the bottle pack during packing at Mylan-Nashik site cannot be established" (official root cause in Trackwise report). Additionally, the email communications between your firm and GQI with all comments and suggestions was not documented in your Quality System.

7. Affiliate Investigation Report 3234763, dated 08/02/2023, was initiated by your firm for complaint regarding "mold on one tablet on one strip" for drug product (b) (4) MG TAB (b) (4) batch number (b) (4) Your firm initiated CQN 3235553, dated 08/02/2023 to prompt review of the investigation by GQI. GQI's comments resulted in your firm adding additional root cause analysis information to the investigation. The email communications between your firm and GQI with all comments and suggestions was not documented in your Quality System.

B. During our inspection, we observed that investigations initiated and performed by your Quality Unit in response to out-of-specification and out-of-trend test results are not always scientifically sound or comprehensive. Furthermore, Corrective Action/Preventive Action (CAPA's) as a result of investigations are not always comprehensive to address root causes or adequately documented to have been performed. For Example:

1. The following laboratory investigations lack adequate root cause analysis and scientific rationale for root cause determined as "sample bias". After your firm performed laboratory and manufacturing investigations, the initial results were invalidated, and two additional sets of (b) (4) testing were performed for in-process product release for further manufacture. Since 2020, approximately (b) (4) commercial batches have been shipped to the US Market with OOS investigations of "Sample Bias".

-LIR 2320589, dated 11/11/2020, and LIR 2328068, dated 12/29/2020 were initiated for OOS results observed in (b) (4) testing for (b) (4) tablets, for batch number (b) (4) The finished product batches were shipped to the US Market.

-LIR 2347690, dated 12/15/2020, was initiated for OOS results in (b) (4) testing for (b) (4) tablets at (b) (4) stage, batch number (b) (4) The finished product batch was shipped to the US Market.

-LIR 2408260, dated 04/16/2021, was initiated for atypical results observed in (b) (4) testing for (b) (4) mg, batch number (b) (4) The finished product batch was used as an exhibit batch (b) (4)

-LIR 2549745, dated 08/26/2021, was initiated for atypical results observed in (b) (4) (b) (4) analysis for (b) (4) Tablets (b) (4) mg, batch number (b) (4) The finished product batch was shipped to the US Market.

2. LIR 2290798, dated 10/06/2020, LIR 2294679, dated 10/10/2020, and LIR 10/15/2020 were initiated for OOS results observed in (b) (4) testing for (b) (4) tablets (b) (4) mg and (b) (4) mg, for semifinished product batch numbers (b) (4) (b) (4) Based on your firm's laboratory and manufacturing investigations, along with a study where the drug product was manufactured on a different equipment (b) (4) versus the equipment (b) (4) used in the OOS batches, your firm determined the likely root cause to be a glitch in the (b) (4) equipment along with variation in relative humidity. Specifically, since the product tested within specification on the (b) (4) your firm concluded that there may have been a glitch in the (b) (4) equipment. Additionally, since the batches were manufactured during monsoon season, your firm concluded that the OOS results may have been

due to variations in RH. Although your firm rejected all batches, and the drug (b) (4) (b) (4) there is no scientific rationale for your root cause conclusion. No trending with respect to RH or equipment was performed by your firm based on the prior (b) (4) manufactured batches of this product and no evaluation of equipment maintenance/performance records were evaluated for the (b) (4) in support of an equipment glitch.

OBSERVATION 3

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. During our review of your Empower 3 chromatography software, interrupted sequences were observed during our review of "Project Integrity Failed" messages, which resulted in "Data Incomplete" chromatographic data. During one such review of, we observed that your firm documented these interrupted sequences via Laboratory Investigation Report 2754152, dated 05/09/2022, showing that no chromatogram/no data had been generated during 3M accelerated (Batch # (b) (4) and 3M long term (Batch # (b) (4) stability testing for sample solutions for finished drug product (b) (4) Capsules (b) (4) mg. However, during your laboratory investigation, the interrupted injections were not adequately documented and/or investigated, in that your firm did not verify the incomplete data chromatograms to evaluate for abnormalities in test data. During the current inspection, we were able to verify the incomplete data, which promoted the software to convert the "data incomplete" chromatograms (no chromatograms observed) to chromatograms observed with elution of principal peaks. Your firm's investigation was inadequate.

Furthermore, this is a repeat deficiency from your 2016 USFDA inspection. Corrective actions

implemented by your firm because of this deficiency included, but not limited to, (b) (4) "Empower Trend Assessment Reports" and (b) (4) "System Audit Trail Review for Empower Application" assessments. Our review of these assessments, which covered the timeframe of the "Project Integrity Failed" message with respect to LIR 2754152, found your firm's corrective actions and review process to be inadequate, in that chromatograms were not brought back (verify incomplete data) and calculations for the sample solution injections were not performed for evaluation of test data.

B. In March 2021, your firm distributed (b) (4) finished product batches of (b) (4) tablets to the US, which contained (b) (4) particles that your firm discovered during compression. According to investigation report number PR 2388377, your firm found the (b) (4) particles in two bulk (b) (4) batch numbers (b) (4) and (b) (4), and you identified the particles as (b) (4) excipient (b) (4) batch number (b) (4) was further manufactured into (b) (4) batch number (b) (4) was also further manufactured into (b) (4) (b) (4)

According to the investigation, the batches were processed through a (b) (4) which rejected 19.89% to 29.10% of each batch primarily due to particles on the outer surface of the tablets. The investigation failed to consider the remaining (b) (4) excipient particles on the interior of the tablets, which are unable to be rejected by the (b) (4) These batches expired in (b) (4)

OBSERVATION 4

Test procedures describing the testing of (b) (4) dosage form drug product are not written and followed.

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Specifically,

Your firm does not record the time samples are collected during dissolution testing of (b) (4) drug products including, but not limited to, (b) (4) Tablets, (b) (4) (b) (4) Capsules, and (b) (4) Tablets. In addition, your dissolution SOP, titled "Procedure for Operation and Calibration of Dissolution Test Apparatus" (number SOP-000550896), does not require analysts to record the time the samples are collected.

OBSERVATION 5

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

Specifically,

A. On 14 May 2024, we observed three (b) (4) particles (foreign material) on the product contact surface in (b) (4) number ESD251 in room (b) (4). This (b) (4) was labeled as in production and was about to be used for (b) (4) Tablets, USP (b) (4) mg / (b) (4) mg), batch number (b) (4) (intended for US market). Your firm identified the foreign material as pieces of the (b) (4) gasket on top of the (b) (4)

B. We observed the following discrepancies on your equipment used for manufacturing tablets and capsules during the week of 13 to 17 May 2024:

-Apparent adhesive and (b) (4) tape debris on the HEPA filter frame above the cleaned bottle conveyor in LAF number EWH037. These cleaned, open bottles were being used as the primary packaging of (b) (4) Tablets, USP (b) (4) mg), batch numbe (b) (4) (intended for US

market), on 16 May 2024.

-Numerous scratches and one pit (with apparent missing (b) (4) on (b) (4) number ESD1516 in room (b) (4) This (b) (4) is used in the manufacturing of (b) (4) tablets USP (b) (4) mg).

-Flaking (b) (4) tape wrapped around wires, which were wrapped around (b) (4) number ESD637 in room (b) (4) This (b) (4) was in "CLEANING" status when observed on 13 May 2024 and it was last used to manufacture (b) (4) batch number (b) (4) (intended for EU market). In addition, your firm does not have an SOP for the use and maintenance of the (b) (4) tape used to wrap around wires.

-Flaking (b) (4) tape wrapped around wires by (b) (4) number ESD252 in room (b) (4) This (b) (4) was in "CLEANING" status when observed on 13 May 2024 and was last used to manufacture (b) (4) Tablets, USP (b) (4) mg (b) (4) mg) (b) (4) batch number (b) (4) (exhibit batch, not for distribution).

-Dents and scratches in (b) (4) number ESD146 in room (b) (4) Drug products manufactured using this (b) (4) include, but are not limited to, (b) (4) (b) (4) Tablets, USP (b) (4) mg / (b) (4) mg) and (b) (4) (b) (4) Tablets (b) (4) mg (b) (4) mg).

-Rough welds above exposed tablets on (b) (4) number ESD509. (b) (4) (b) (4) Tablets, USP (b) (4) mg), batch number (b) (4) (intended for New Zealand market), were being processed when this (b) (4) was observed on 14 May 2024.

OBSERVATION 6

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

Specifically,

On 14 May 2024, we observed pits, scratches, and chips, ranging from 0.5 to 6 inches wide, some of which contained (b) (4) debris, in the (b) (4) flooring in the ISO 8 production corridors, including, but not limited to, in front of Compression (b) (4) (room number (b) (4) Suite (b) (4) (room number (b) (4) (room number (b) (4), and (b) (4) Area (b) (4) room number (b) (4) In addition, a pit approximately one inch in diameter was observed in the (b) (4) floor in the (b) (4) room (room number (b) (4) All tablets and capsules manufactured by your firm are manufactured in rooms connected to the ISO 8 production corridor.

OBSERVATION 7

Records associated with drug product production and control and within the retention period for such records, were not made readily available for authorized inspection.

Specifically,

Per your firm's SOP-000768572, titled "Communication of Critical Quality Events", a Critical Quality Notification (CQN) is initiated by your firm to your Global Quality Investigation (GQI) team, to report a Critical Quality Event (CQE), which per your firm's procedure is an incident which may impact the quality, safety, efficacy, or purity of commercially distributed products.

-On 05/14/2024, a discussion was held regarding these procedures and practices, where your firm explained that, after issuing a CQN, the firm performs their investigation in TrackWise software, after which the GQI team (corporate) performs a review of the firm's investigation, providing feedback.

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After this feedback, on site corrections are made, and the investigation is closed with signatures from a quality member at your firm and a signature from a member of GQI in TrackWise.

-On 05/14/2024, when we asked how feedback from GQI is communicated to the firm, your firm personnel mentioned, through voice conferences and video conferences. When we further asked if any feedback was provided via email communications, a senior member of your Quality Unit responded, "They send a softcopy, final copy loaded to TrackWise". This statement was further explained, where your firm personnel send an email with the draft written investigation, after which GQI reviews the draft investigation, with track changes/comments, and sends the attached draft investigation with suggested changes back to your firm's quality team.

-On 05/14/2024, I requested for the firm to provide all email communications with respect to all investigations that we would request throughout the inspection. On 05/15/2024, select CQN investigation reports were selected from a list provided by your firm and requested for review, with reiteration to provide all feedback documentation, including email communications. On 05/15/2024, when we started to review these CQN investigations, your firm stated that there were no email communications/attachments and that everything was done in Trackwise, with feedback provided by phone and video conferences between the firm and GQI which are not recorded. We reviewed too numerous to list CQN investigations on 05/15/2024 and 05/16/2024 without documentation of feedback between your firm and GQI.

-On 05/20/2024, we discussed the topic of email communications further, and we requested your firm's official statement on not having or having any email communications with draft investigations for any CQN's. Shortly after, your firm's senior management on site attempted to communicate with a senior level of your Global Quality Team to discuss our concerns and provide an answer to our question, where emails are sent with draft investigations. After your firm stated, you would need four hours to provide an answer, a discussion was held on why your firm needed 4 hours, let alone any amount of time to discuss the existence of emails between your site and GQI with a member of Global, since the firm's

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entire Quality Unit was available to discuss its CQN operations. Immediately after this discussion, your firm confirmed the existence of email communications containing draft investigations between your firm and GQI. From 05/20/2024 to 05/23/2024, we reviewed CQN's with email communications, at times, re-reviewing CQN investigations which we had reviewed the week prior.

-These events and interactions detailed in this section introduced a delay in our ability to perform the remainder of the inspection in a timely and effective manner.

***DATES OF INSPECTION**

5/13/2024(Mon), 5/14/2024(Tue), 5/15/2024(Wed), 5/16/2024(Thu), 5/17/2024(Fri), 5/20/2024(Mon), 5/21/2024(Tue), 5/22/2024(Wed), 5/23/2024(Thu), 5/24/2024(Fri)

X Wayne D Mcgrath
Investigator
Signed By: 2001897192
Date Signed: 05-24-2024 02:59:10

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Arsen Karapetyan, Investigator - Dedicated Drug Cadre Wayne D Mcgrath, Investigator	X Arsen Karapetyan Investigator - Dedicated Drug Cadre Signed By: Arsen Karapetyan -S Date Signed: 05-24-2024 02:58:15	5/24/2024