DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave,Bldg 51,Rm 4225 Silver Springs, MD 20993 (301)796-3334 Fax:(301)847-8738	9/5/2016-9/14/2016* FEI NUMBER 3005587313

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Uday B. Kasbekar , Head of OSD Site Operations - Nashik

FIRM NAME	STREET ADDRESS
Mylan Laboratories Limited, (Nashik FDF)	F-4 F-12, Malegaon M.I.D.C., Sinnar
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Sinnar, Nashik District, Maharashtra, 422113India	Finished 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 I OBSERVED:

OBSERVATION 1

The accuracy, sensitivity, specificity and reproducibility of test methods have not been established and documented.

(a) Analytical methods used to ensure the quality of drug products are not validated prior to their transfer from your firm's (b) (4) facility. For example, the following analytical procedures were transferred to the Quality Control Laboratory prior to completing method validation:

Product Name	Strength	(b) (4) no.	Analytical Test Method	Date of Method Validation	Date of Method Transfer from (b) (4) to Nashik
(b) (4) Tablets USP	(b) (4) mg, (b) (4) mg and (b) (4) mg	(b) (4)	MVR (b) (4) -BAY-006/00 MVR (b) (4) -AY-01 5/00 MVR (b) (4) -DS-014/00 MVR (b) (4) -RES-012/00 MVR (b) (4) -RS-01 6100	19/07/2010 21/11/2012 21/11/2012 12/11/2012 30/11/2012	29/07/2010
(b) (4) Tablet	(b) (4) mg	(b) (4)	MVR (b) (4) -AY-001/00 MVR (b) (4) -DS-003/00 MVR (b) (4) -RS-002/00	22/01/2009 09/04/2009 12/02/2008	5/11/2007
(b) (4) Tablets	(mg & (b) (4) mg	(b) (4)	MVR (b) (4) -DS-002/01 MVR (b) (4) -AY-003/01 MVR (b) (4) -RS-004/02	11/05/2015 11/05/2015 11/06/2015	19/04/2012 23/05/2012

Consistent with SOP GADS016-10 ("Procedure for Transfer of Analytical methods") and examples above, your firm's Quality Unit transferred methods prior to their validations for the majority of recently submitted and approved (b) (4) submitted to the Agency.

Furthermore, in multiple instances, your firm's Quality Unit approved and undertook analysis (i.e., GMP testing) of drug products at the Nashik manufacturing facility prior to ensuring the validity of the methods. Some examples are below. Your

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firm's Head of Global OSD Scientific Affairs, Product Development stated that it is common practice to initiate testing of drug products prior to validation:

Product Name	(b) (4) no.	Analytical Test Method	Validation	Date of First GMP Testing
(b) (4) Capsules USP	(b) (4)	MTW-(b) (4)-004	14/01/2011	28/10/2010
(b) (4) Capsules	(b) (4)	MVR-(b) (4) -AY-004/00	25/03/2014	29/08/2013
(b) (4) Tablets	(b) (4)	MVR-(b) (4) -DS-002/01	11/05/2015	25/09/2014

(b) I observed anomalies in the dating of various method transfers and method validations as follows:

I. The testing protocol to transfer the analytical method of (b) (4) Capsule is dated June of 2012 (document FPP(b) (4) 106R-00) with a method transfer date completed in September 2012. However, the testing protocol to complete the analytical method validation is dated February of 2013 (MVP-(b) (4) -AY-003/00) with a method validation date of March 2014. According to these dates, the method was transferred from the (b) (4) facility to the Nashik manufacturing facility prior to its validation or even validation testing protocol. Stability testing submitted to the Agency was performed prior to method validation. Additionally, the submission batch (b) (4) was manufactured prior to validation.

Additional, similar examples of such anomalous dating were observed with the testing procedures for (b) (4) Tablets and (b) (4) Tablets.

II. Your firm's Quality Unit prepared and approved method transfer protocols prior to the generation of approved STPs for the following drug products:

(b) (4) Tablets
(b) (4) Tablets
(b) (4) Capsules USP
(b) (4) Tablets USP
(b) (4) Tablets
(b) (4) Tablets USP
(b) (4) Tablets

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This practice is inconsistent with the prospective method validation approach described by your firm in "Process Flow for Method Validation and Method Transfer", which states method validation precedes method transfer.

(c) On September 7, 2016, your firm's Head of Quality API & OSD – India stated that no testing is performed at the (b) (4) (b) (4) located in (b) (4) once validation is completed. Similarly, your firm's Head of Regulatory Science OSD stated that the (b) (4) facility is solely for method validation.

However, a review of test injections performed on the (b) (4) Laboratory HPLCs through the company-wide server at Nashik revealed numerous instances of drug product testing for the following products (the pages designation indicates the number of pages obtained upon exporting injection history from the Empower 2 software – approximately 10 injections per page):

Product	Pages
(b) (4) and (b) (4) Tablets	(b) (4)
(b) (4) Tablets	
(b) (4) and (b) (4) Tablets	
(b) (4) Capsules	
(b) (4) Capsules	
(b) (4) Capsules	
(b) (4)	
(b) (4) Tablets	
(b) (4) Tablets	

The examples cited above are for the time period of July through August of 2016. There is no documentation to support that any of the test methods used to analyze these products are currently being revalidated (with the exception of (b) (4) and (b) (4) Tablets), and no evidence was provided for drug product testing of these products at the (b) (4) facility continuing despite a completed validation.

(d) Validated laboratory methods do not provide consistent and reliable test results. For example:

I. OOS investigation PR 808607 for assay of (b) (4) states "In order to avoid the variability in the assay results, a CAPA (917679) was assigned to ADS ((b) (4)) to re-visit the analytical method for assay test." Your firm's

management stated that the report refers to the assessment of suitability of the method for analytical testing. (b) (4) (b) (4) has been tested approximately (b) (4) times (including for stability) prior to this OOS.

II. OOS investigation PR 859912 for (b) (4) content in (b) (4) and (b) (4) tablets stated to "Discard first (b) ml of (b) (4) ." Your firm's General Manager – Quality Control Compliance explained that the protocol lacked sufficient detail. This OOS investigation states that the STP will need to be updated to include this information. Prior to this OOS, (b) tests had been conducted utilizing this method and provided to FDA in support of an (b) (4) .

III. OOS Investigation PR 730461 for related substance testing of (b) (4) and (b) (4) tablets determined that "results obtained by modified test preparation gives more reproducible results compare to results obtained by test preparations as per current STP." Prior to PR 730461, (b) (4) samples of (b) (4) and (b) (4) tablets had been analyzed for related substances.

IV. OOS investigation PR 689665 for related substances in a sample of (b) (4) Capsule concludes with a CAPA to "revise the product test procedures." Prior to this OOS, (b) (4) samples of (b) (4) and (b) (4) tablets had been analyzed for related substances.

In 2016, 8 of 14 CAPAs resulting from incidence reports are related to implementing changes to sample preparation within the methods. As noted above, several OOS results were attributed to failures to adequately prepare samples for analytical testing. The variability in sample preparation has not been assessed by the Quality Unit.

OBSERVATION 2

There is a failure to thoroughly review 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, Out of Specification test results for US marketed drug products were invalidated without sound scientific justification. For example:

(a) OOS report PR 801873 was opened for an out of specification result of (b) (4) % for assay of (b) (4) and (b) (4) Tablets (18 month stability). The assay specification is (b) (4) – (b) (4) %. Initially, "no apparent laboratory error was identified." However, the report later conversely concluded that "execution error could be spillage of sample." However, the assay of (b) (4) tested with the same sample that provided the OOS result yielded results that were within specification. Nonetheless, this justification was used to invalidate the initial failing results and utilize the passing retest results.

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(b) OOS report PR 879521 was opened for out of specification and out of tolerance results for assay of (b) (4) and (b) (4) Tablets (12 month stability). The report initially concluded "no obvious reason and probable cause identified for OOS/OOT results." A retest was performed and the results were within specification. The final conclusion was that the root cause was laboratory error and the initial OOS results were invalidated.

Note multiple OOS and OOT results were a part of this report.

(c) OOS report PR 908027 was opened for an initial out of specification for assay of (b) (4) Tablets (6 month stability) for a result of (b) (4) %. The specification is (b) (4) – (b) (4) %. Although the report states that "The results of phase-1 analysis does not conclude any laboratory error during analysis," the report then conversely concludes that the error "probably could be due to spillage of sample solution." This justification was used to invalidate the initial failing results and the retest results were accepted as the final reported test result.

(d) OOS report PR 876239 was opened for out of specification and out of tolerance results for assay of (b) (4) Tablets. The report indicates "no laboratory error was identified for initial atypical result". The report then conversely concludes "laboratory error." Nonetheless, the report concludes the root cause is laboratory error and the initial results were invalidated and retest results were utilized.

(e) OOS report PR 915172 was opened for an out of specification result for (b) (4) content of (b) (4) Tablets. The report confirms the OOS and failure to meet internal specification, yet the product was released for distribution. The report acknowledges the product was "not complying with product release specification."

Additional examples of deficient invalidation of failing results were observed. Moreover, the aforementioned failures mostly relate to assay results. In 2016, assay data accounted for approximately 54.5% of unconfirmed OOS results, but only approximately 24% of confirmed OOS results. The majority of invalidated assay results are attributed to sample preparation (mostly shaking of flasks); however, no CAPA or investigation has been implemented to address or correct these issues.

T THIS IS A REPEAT OBSERVATION FROM THE PREVIOUS INSPECTION

OBSERVATION 3

Your electronic records for your production and process control system do not comply with the electronic records requirements.

Manufacturing data from the PLC related to the manufacture of (b) (4) for (b) (4) is absent.

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Your firm's process validation of (b) (4) for (b) (4) utilized batches (b) (4), (b) (4) and (b) (4) on the compression machine ESD 416, which is operated by an (b) (4) Programmable Logic Controller (PLC). This PLC has a record for batch (b) (4), but not for batches (b) (4) and (b) (4). Based on the lack of a record in the PLC, there is no evidence that batches (b) (4) and (b) (4) were actually produced on the compression machine ESD 416, as stated in the process validation report for (b) (4), Document No. PV/TAB/25/02/15.

Note: data pertaining to a number of batches preceding batch (b) (4) was available, demonstrating that data retention was not the reason for the absence of data pertaining to batches (b) (4) and (b) (4).

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.

Your firm has not ensured that analytical laboratory data is preserved.

(a) In August 2016, two incidences of "Deleted Result Set" were observed by an individual with "Reviewer" designation. These incidences were associated with assay of (b) (4) batch (b) (4) and (b) (4) and (b) (4) Tablets identified (b) (4). No investigation or CAPA was initiated for these two incidences by the Quality Unit. Your firm's Assistant General Manager - Producer (b) (4) indicated that a comprehensive assessment of audit trail messages had not been assessed during validation of Empower 3.

(b) No investigation is conducted into identifying and solving the root cause of missing data points - At the time of my inquiry during this inspection, there had been approximately 160 incidents of "Project Integrity Failed" in your Empower 3 system audit trail since the beginning of calendar year 2016. Your firm's employees, including the Deputy Manager – Quality Assurance, identified that these "Project Integrity Failed" messages are related to the incidences of "One or more injections are missing." This situation has led to this warning of missing injections in more than 115 incidents. In multiple instances, this warning occurred multiple times throughout a run.

For example, in the analysis of (b) (4) for (b) (4) and (b) (4) Tablets batch (b) (4) (June 20th, 2016) this "Project Integrity Failed" rendered no chromatogram for the initial run (only

a "Data Incomplete" display) and there has been no investigation into this incident or the fact there is no chromatogram.

In a number of other cases, an investigation was opened, but no root cause was identified and no CAPA was opened to prevent recurrence of the "Project Integrity Failed" messages.

Additional examples of incidents and the corresponding conclusions are listed below (these incidents are from 2016 alone):

(b) PR 943693 – Describes a "Connection to chromatography system lost" event in the analysis of (b) (4) . The initial data acquired was invalidated due to the loss in connectivity.

(c) PR 947661 - Describes a "Connection to chromatography system lost" event in the analysis of (b) (4) API. The initial data acquired was invalidated due to the loss in connectivity.

(d) PR 931672 – Describes a "instrument malfunction" during the run of (b) (4) Tablets. The initial data acquired was invalidated due to the malfunction.

Additionally incidents PR 989728, 980190 and 989509 were related to "power loss" of specific HPLCs during the acquisition of analytical data. The initial data acquired was invalidated due to power loss.

(c) Within the Empower 3 messages center log from August 29th, 2016 to September 5th, 2016, I observed approximately 150 messages indicating "Possible data corruption or modification of file" affecting 12 sequences. Moreover, during this same period, connectivity to the system was lost on two occasions. No CAPA or investigation has been opened to address these incidents of "Possible data corruption or modification of file." Data was lost, as it was not captured in a back-up system.

(d) I reviewed your firm's "COMPUTER SYSTEM VALIDATION PLAN FOR WATERS EMPOWER 3 CDS" dated 09/10/2015. On this report, under section 1.4 termed "Assumptions" it is stated "Direct testing of the hardware, operating system software, communication software, and network components is not included as these are indirectly tested during validation testing." There were reoccurrences of communication errors demonstrates observed throughout the inspection.

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OBSERVATION 5

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

Investigation of complaints is deficient.

(a) Upon trending complaints for 2016, I identified that lots (b) (4) and (b) (4) of (b) (4) Tablet had 5 associated complaints related to the category "Tablet Broken or Chipped." On 13.04.16, batch (b) (4) "passed" 100% visual examination. I reviewed reports PRs 944122 and 986459 related to complaints for lot (b) (4) and did not observe a comprehensive evaluation, including identifying the size of the chip or consideration of formulation factors. This complaint type has been deemed a "Recurring Event/Trend."

I reviewed SOP MLLNSK-SOP-QA-GMP-0120 entitled "HANDLING OF COMPLAINTS" with your firm's General Manager – Quality Assurance. He specified that (b) or more complaints for the same lot was a threshold for investigating "Major" of "Minor" complaints, in order to differentiate isolated events. On 09/08/2016, I observed multiple chipped tablets in a single (b) (4) tablet bottle of retained (b) (4) Tablet lot (b) (4)

Your firm's Head of OSD Site Operations – Nasik stated that your firm has opened a comprehensive CAPA and made significant efforts to identify the source of the broken and chipped tablets. However, the inspection was conducted in March 2015 and this CAPA was conducted in June 2016, when additional complaints related to broken or chipped tablets were obtained. Additionally, these investigations are deficient in not considering the aforementioned factors. Furthermore, this report concludes that "As the compression observations ((b) (4)) and AQL observations are within specifications, breakage of single tablet (in the reported complaint), cannot be attributed to a process or product defect."

However, on 09/11/2106, I observed the (b) (4) of the filling line for (b) (4) Tablets, where tablets had abrasions in the (b) (4) . Additionally, I observed significantly chipped tablets pass through the tablet (b) (4) (to be destined for further bottling). Nonetheless, the "AQL" (and 100% visual inspection) was deemed passing. These occurrences are indicative of deficiencies in your firm's visual inspection, as well as ensuring drug product quality.

(b) (b) (4) tablets batch (b) (4) had two associated complaints. In one instance, no sample was retrieved for analysis. In the complaint PR 632630, the complaint concludes that "As some pieces match to form complete tablets" the incident is not related to your Nashik facility (as all the pieces to the broken tablet were in the bottle, therefore the issue is unrelated to your manufacturing facility). Your firm's General Manager – Quality Assurance explained that as all fragments are contained within the bottle, therefore the cause of the broken tablets is shipping. Your investigation into this matter failed to

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consider other possible causes of the incidents, including the drug product formulation or issues during manufacturing that may have led to the presence of broken tablets.

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OBSERVATION 6

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

All clean equipment observed displayed deficient cleaning.

(a) On September 11, 2016, I observed a non-dedicated compression machine (ID # ESD 743) with a "CLEANED" status tag. This equipment had white residue where the (b) (4) the compression machine (a product contact surface). This equipment is used in the manufacture of multiple drug products, including (b) (4) tablets for the US market.

(b) On September 12, 2016, I observed a non-dedicated (b) (4) machine (ID # ESD 1077) with a completed "CLEANING CHECK LIST". This equipment had white residue around the (b) (4) and on the (b) (4) (a product contact surfaces), which was also observed by the Head of OSD Site Operations – Nasik. Additionally, the gasket lining in the equipment was observed to be damaged. This equipment is used for (b) (4). The Head of OSD Site Operations – Nasik stated that this was drug product residue. This equipment is used in the manufacture of multiple drug products, including (b) (4) tablets for the US market.

*DATES OF INSPECTION

9/05/2016(Mon),9/06/2016(Tue),9/07/2016(Wed),9/08/2016(Thu),9/09/2016(Fri),9/11/2016(Sun),9/12/2016(Mon),9/13/2016(Tue),9/14/2016(Wed)

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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."