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SUMMARY

This was a limited inspection of Mylan Pharmaceuticals, Inc., a manufacturer of generic solid oral dosage forms. This inspection was conducted in follow-up to a newspaper article alleging that the computerized manufacturing quality controls were overridden at the firm. FACTS assignment [redacted].

The previous biennial GMP inspection was conducted from 11/26/07 – 12/13/07. The inspection was classified NAI.

At the initiation of the current inspection on 7/27/09, an FDA-482, "Notice of Inspection" was issued and credentials were presented to Mr. Richard D. Glover, Vice President, Quality and most responsible person present for the plant at the time of the inspection. The inspection covered the use of the Laboratory Information Management System (LIMS) for in process physical testing of capsules and tablets. Records reviewed included, but were not limited to data screens from LIMS, Standard Operating Procedures (SOPs), training files, and organizational charts. On 7/28/09, at the direction of Baltimore District Management a close out meeting was held with management. No significant discrepancies were observed and no FDA 483 was issued.

On 7/29/09, I returned to the facility at the direction of Baltimore District Management and an FDA-482, "Notice of Inspection" was issued and credentials were again presented to Mr. Richard D. Glover, Vice President, Quality and most responsible person present for the plant at the time of the inspection. This part of the inspection covered the use of the LIMS for in process physical testing of capsules and tablets. Records reviewed included, but were not limited to data screens from LIMS, Standard Operating Procedures (SOPs), batch records, laboratory notes, certificates of analysis, training files, chromatograms, raw data, and organizational charts.

The firm's investigation found that all the LIMS red screen incidents where the SOP was not followed regarding the Supervisor being contacted and present for the retest and entry of the data into the LIMS system involved obvious errors where no manufacturing equipment adjustments were necessary; that no data was deleted and the audit trails were intact, and that the lack of adherence to the current SOP has not resulted in any adverse impact to product quality.

On 7/30/09, a second close out meeting was held with management. No significant discrepancies were observed and no FDA 483 was issued.

There were no refusals, warnings. There were no voluntary corrections from the previous inspection. There were no samples collected.

ADMINISTRATIVE DATA

Inspected firm:	Mylan Pharmaceuticals Inc.
Location:	781 Chestnut Ridge Road Morgantown, WV 26505-2730
Phone:	304-599-2595
FAX:	(304)598-5407
Mailing address:	P.O. Box 4310 781 Chestnut Ridge Road

Morgantown, WV 26504-4310

Dates of inspection:	7/27/2009, 7/28/2009, 7/29/2009, 7/30/2009
Days in the facility:	4
Participants:	William A. Warnick, Investigator

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On 7/29/09, I returned to the firm and a second FDA-482, "Notice of Inspection" was issued and credentials were again presented to Mr. Richard D. Glover Vice President, Quality and most responsible person present for the plant at the time of the inspection.

HISTORY

Mylan Pharmaceuticals Inc. continues to operate as a subsidiary of Mylan Inc. which is incorporated in Pennsylvania. Mylan Pharmaceuticals Inc. was founded and incorporated in West Virginia in 1961. Mylan Pharmaceuticals Inc. moved to its present location in Morgantown, WV in 1965. Mylan Pharmaceuticals Inc. became a publicly traded company in 1973.

There is no record of regulatory actions against the firm in the file jacket.

There have been no recalls concerning the products covered in this limited inspection. A list of products covered can be found on pages 11 – 14 of this report.

The firm is currently registered as a manufacturer of human drugs under FEI: [redacted].

A list of related firms was not obtained during this limited inspection.

POST INSPECTIONAL CORRESPONDENCE:

The most responsible person for the firm present was Mr. Richard D. Glover, Vice President, Quality. Correspondence should be addressed to him at:

Mylan Pharmaceuticals, Inc.
P.O. Box 4310
Morgantown, WV 26504-4310

INTERSTATE (I.S.) COMMERCE

The firm ships [redacted] percent of finished products to its related warehouse in Greensboro, NC.

JURISDICTION (PRODUCTS MANUFACTURED AND/OR DISTRIBUTED)

Mylan Pharmaceuticals, Inc. is a manufacturer of generic solid oral dosage forms which include capsules and tablets. The firm manufactures under the Mylan brand name. Profile classes for this firm are: [redacted], and [redacted].

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

I collected copies of the current organizational flow charts for Mylan Pharmaceuticals Inc., manufacturing and quality **(Exhibits 1 & 2)**. I also collected a copy of the Mylan, Inc. organizational flow chart **(Exhibit 3)**.

Ms. Patricia M. Latzo stated that she is the Senior Vice President Global Quality, Mylan, Inc. She is responsible for leadership of the firm's quality, developing and applying quality systems, and supervising the firm's operation, compliance and project management functions for quality both globally and regionally. She reports to Executive Vice President Global Technical Operations, Rajiv Malik. I collected a copy of the position description for the SVP, Global Quality **(Exhibit 4)**. Ms. Latzo was present and participated in the inspection.

Mr. Kevin A. Kolar stated that he is the Vice President, North America Quality, Mylan, Inc. He is responsible for implementing the firm's quality system in the firm's North American operations. He reports to Senior Vice President Global Quality, Mylan, Inc., Patricia M. Latzo. I collected a copy of the position description for the Vice President, NA Quality **(Exhibit 5)**. Mr. Kolar was present and participated in the inspection.

Mr. Richard D. Glover stated that he is the Vice President, Quality, Mylan Pharmaceuticals Inc. He is responsible for developing, maintaining the firm's quality system and compliance strategy and overall quality at the firm. He reports to the Vice President, North America Quality, Mr. Kevin A. Kolar. I collected a copy of the position description for the Vice President, Quality **(Exhibit 6)**. Mr. Glover was present and participated in the inspection. Mr. Glover answered my questions through out this inspection.

Mr. [redacted], stated that he is an Assistant Manager, Compressing, Mylan Pharmaceuticals Inc. He is responsible for manufacturing compliance with SOPs, GMPs and ensuring consistent quality of Mylan products. He reports to Compressing Manager, Mr. [redacted]. I collected a copy of

the position description for Assistant Manager, Compressing **(Exhibit 7)**. Mr. [redacted] answered my questions during this inspection.

Mr. [redacted], stated that he is Department Coordinator, Compressing, Mylan Pharmaceuticals Inc. He is responsible for coordinating tablet press operations. I did not ask him to whom he reports. I collected a copy of the position description for Department Coordinator, Compressing **(Exhibit 8)**. Mr. [redacted] answered my questions during this inspection.

Mr. [redacted], stated that he is a Tablet Press Operator, Compressing, Mylan Pharmaceuticals Inc. He stated that he was responsible for operating a tablet press and conducting in process physical testing. I collected a copy of the position description for Tablet Press Operator **(Exhibit 9)**. Mr. [redacted] answered my questions during this inspection.

Mr. [redacted] stated that he is a Tablet Press Operator, Compressing, Mylan Pharmaceuticals Inc. He stated he was responsible for operating a tablet press and conducting in process physical testing. I collected a copy of the position description for Tablet Press Operator **(Exhibit 9)**. Mr. [redacted] answered my questions during this inspection.

FIRM'S TRAINING PROGRAM

The firm conducted training entitled [redacted] **(Exhibit 10)** on 5/26/09 – 5/29/09 and "[redacted]" **(Exhibit 11)** on 6/08/09 – 6/10/09 as part of their corrective and preventive actions in response to their investigation concerning improperly handled red screens for in process physical testing.

Other training was not covered during this inspection.

MANUFACTURING/DESIGN OPERATIONS

On 7/27/09, I told Mr. Richard D. Glover, Vice President, Quality, that I was conducting a limited inspection concerning allegations raised in a newspaper article that quality controls had been overridden for weight, thickness and hardness. Mr. Glover stated the firm's investigation found that all the so-called LIMS red screen incidents involved obvious errors such as broken tablets, tablet or capsule bouncing off the scale, leaning on the chute from the vibratory feeder where no manufacturing equipment adjustments were necessary. He stated that no data was deleted and the audit trails were intact.

Mr. Glover explained that the operators had used the right click feature in LIMS to correct these obvious errors. He stated the right click feature was an electronic version of crossing out a data entry with a single line, initialing the entry, entering the correct data and providing a reason for the correction that was performed when the records were kept by hand on paper. He stated the operators

were permitted to use the right click feature to change inaccurate information such as an incorrect box number for the tablets or capsules sampled. He stated that the right click feature is a normal part of the LIMS software. He said Management was not aware that the right click feature could be used to correct red screen data errors until the firm's investigation was conducted.

I asked Mr. Glover what functions the LIMS system has in the firm's operations. He stated that the software was used to capture and store data from in-process physical testing in the manufacturing environment.

I collected a copy of Mylan [redacted] LIMS Version [redacted] Validation Strategy Document dated [redacted] **(Exhibit 12)**. The document states under "3. SYSTEM DESCRIPTION" that "The data collection station's primary roles are that of raw data capture, data verification, and process feedback for the equipment operator. As the data is tested and captured from interfaced measuring devices, the data collector compares each reading and subsequent calculated results against entered product limits. Warning messages are displayed when statistical trends, product specifications, or other defined limits are violated."

LIMS software does not control any manufacturing equipment; it collects and stores in-process data for physical testing only. The operator must shut down any manufacturing equipment according to the appropriate SOP if an Out of Specification (OOS) result occurs.

The LIMS software incorporates the use of a yellow screen when a result is outside of the firm's specified control range. The firm sets the "Out of Control" limits in the software to a tighter range than an OOS result. This alerts the operator if product is moving toward being OOS, so action can be taken before the product reaches the OOS stage. The software incorporates red screens to alert the operator that the test result is OOS.

Mr. Glover provided me with a copy of the firm's presentation on how the right click feature was used to clear a LIMS red screen as opposed to following the appropriate SOP and getting a Supervisor **(Exhibit 13)**. The right click feature is an integral part of the LIMS software as it was delivered by [redacted]. The presentation shows the screens that display how some of the operators used the right click, to cut and replace the original data. When the original data is cut it is automatically archived in the audit history. The system requires the operator to specify a reason for the change, before the system saves the data. The presentation shows a screen of the audit trail for the data which was corrected without following the firm's SOP, similar to those for the actual red screen data **(Exhibits 19 & 22 -73)**. The presentation also has examples of the screens used when the operator follows the SOP and the Supervisor is contacted and is present for the retest and entry of the data into the LIMS system.

I asked Mr. Glover if the LIMS system was used in other areas of the firm including the laboratory. Mr. Glover stated that the firm had started using LIMS in the laboratory on [redacted], but the system

was currently only being used to generate sample numbers. He stated that LIMS was not being used to capture analytical data at this time.

I asked Mr. Glover how the firm had discovered that the operators used the right click feature. He stated that the firm discovered the operators' use of the right click feature on [redacted] when a Quality Assurance (QA) Associate Manager noticed a red screen without the required LIMS investigation performed by a Supervisor. The QA Associate Manager notified the Supervisor of the red screen and the Supervisor said he was not notified of the red screen as required by the [redacted] "[redacted]" Effective date: [redacted] **(Exhibit 14)**.

INVESTIGATION PR #32885

Investigation [redacted] **(Exhibit 15)** was initiated for lot [redacted], Extended Phenytoin Sodium capsules on (date). The firm determined that a total of four red screens were improperly bypassed without Supervisor notification during the manufacture of lot [redacted], Extended Phenytoin Sodium Capsules, USP. I reviewed the SOP mentioned above for investigating OOS results and the documentation for the firm's Investigation [redacted] and had no objectionable observations.

The firm determined that two improperly handled red screens had occurred during the physical testing of box [redacted] of the batch. Upon this determination, box [redacted] was put on QA hold and the top, middle and bottom of the box were resampled. Weights were taken and found to be within specifications. The firm determined another single red screen event without Supervisor notification for box [redacted] Box [redacted] was put on QA hold and the top, middle and bottom of the box were resampled. Weights were taken and found to be within specifications.

The firm's review of the data for the entire lot determined that red screen events had also occurred for boxes [redacted] and [redacted] of the batch. The firm concluded that the red screen events for boxes [redacted] and [redacted] had been properly handled following the firm's SOPs. Box [redacted] had two red screen events without Supervisor notification, and was put on QA hold. The top, middle and bottom of box [redacted] were resampled and weights were taken and found to be within specifications. Screen prints from the original weight samples for boxes [redacted] were canceled **(Exhibits 16 -18)**. The data still resides in the LIMS system; however the firm invalidated the results of the original weight testing with improperly handled red screens. I collected and reviewed screen prints **(Exhibits 16 -18)** of the data from the incident on [redacted] that led to investigation [redacted] **(Exhibit 19)**. I had no objectionable observations.

Mr. Glover stated that they had held meetings on [redacted] for the first and second shifts and on [redacted] for the third shift to inform all employees that red screen data was not be cleared using the right click feature of the LIMS software.

The firm expanded their investigation and searched for improperly handled red screens back through [redacted] or approximately [redacted] months. Mr. Glover stated that they found [redacted] employees that had used the right click feature to make corrections to the physical testing data. He stated they interviewed all employees and determined that they had only used the right click feature to correct the physical testing data when they had witnessed an obvious error, such as a balance incident, or a tablet not properly positioned in the test device for a thickness measurement or hardness test.

The firm created an Executive Summary for the investigation including information on the background, immediate preventive actions, employee interviews, product impact assessment, conclusion, and long term corrective and preventive action **(Exhibit 20)**. I asked Mr. Glover why the firm had not looked further into the previously affected batches and he said that due to the low number of red screens, the investigation and interviews with the operators and the independent QC data collected and analyzed for each batch, that they were confident there were not any quality issues due to the red screen events. I reviewed the Executive Summary and had no objectionable observations.

I requested a list of all LIMS red screens for the previous year where Supervisors had not been notified according to the firm's SOPs. During the investigation the firm searched the LIMS system for all improperly handled red screens [redacted] months back through [redacted]. Initially I reviewed [redacted] red screen events from the firm's investigation and spot checked two others within the past [redacted]. I found that for each event the original data was present, the corrected data was present, there was a reason for the change, date, time and operator identification stamp were present for each data point.

I then collected a list of all the LIMS red screens where Supervisors had not been notified according to the firm's SOPs going back to [redacted] when the LIMS system had been fully implemented for physical testing in the firm's compressing and encapsulation departments **(Exhibit 21)**. The list includes information concerning the product, lot number, whether the product is on stability, complaints, investigations, the LIMS sample number for which the red screen occurred, date, result name, before and after reading, total physical tests per lot, and which operator the result was changed by.

I reviewed batch records for lot [redacted] Divalproex Sodium Delayed Release Intermediate Pellets and for lot [redacted] Ciprofloxacin Tablets, USP 500 mg. The review included raw data for finished product testing. I had no objectionable observations.

Including lot [redacted], Extended Phenytoin Sodium Capsules, USP which led to the investigation, there were [redacted] lots in the past year which had red screens cleared without following the appropriate SOP. I reviewed and collected screen prints of the data for each of the improperly handled red screen events found during the firm's investigation **(Exhibits 22 - 40)**. I reviewed and collected screen prints of the data for the 33 improperly handled red screen events prior to their investigation

going back to when the LIMS system had been fully implemented on [redacted] **(Exhibits 41 – 73)**. I found the original data was present, the corrected data was present, there was a reason for the change, date, time and operator identification stamp were present for each data point. The operator identification for the original reading matched operator identification for the corrected reading in each incident. On each screen print, the operator's identification for the initial data and the retest data matched. I asked why the calculations for the average readings caused a red screened to occur and Mr. Glover stated that when a data point within the calculation changed, the calculation result would red screen. The red screen for the calculation error could be cleared by rerunning the calculation with the revised data. I had no objectionable observations.

I summarized the reason for the data change by the Result Name listed for "[redacted]" **(Exhibit 21)**:

Result Name	Number of Red Screen Occurrences
Weight	43
Average Friability	3
Fill Weight	2
Average Shell Weight	1
Weight of Capsule and Fill	1
Thickness	1
Average Thickness	1

I summarized the reason for the data change by the audit phrase listed in the screen prints **(Exhibits 19 & 22 -73)** of the red screen events which had not been cleared following the proper SOP for [redacted].

Red Screen Audit Phrases	Number of Instances Cited
Operator Error	43
Instrument Error	2
Calculation Update	7
confirmation	1
TOTAL	53

I asked Mr. Glover what audit phrases were available and he provided a list: [redacted] **(Exhibit 74)**. He stated that Operator Error, Calculation Error, and Instrument Error were canned language from the system. He said that the system would accept custom language and that is how the "confirmation" was entered. The "confirmation" was custom language entered by the operator when the initial weight of a tablet was recorded as [redacted] and was replaced with [redacted]. I asked him for the

meanings of the different audit phrases and he stated there were no definitions in writing. He stated Operator Error was an obvious error by the operator. He stated a Calculation Error was due to a data point or points being corrected; for example a calculation of average capsule weight had to be rerun. He stated Instrument Error was used by an operator when the instrument was improperly used, such as leaving the door open on an enclosed balance. He stated "No reason specified" was the default language used when the record was reviewed.

I asked Mr. Glover if there were any complaints for any of the lots involved in the red screen incidents with SOP deviations. He stated that there were no complaints involving these lots. I asked him if any of the lots involved in the red screen incidents with SOP deviations had been recalled. He stated that none of the lots had been recalled.

I asked Mr. Glover if any of the lots were placed on stability. He provided a list **(Exhibit 21)** of products showing that [redacted] of the [redacted] lots were placed on stability. I asked if there had been any stability failures. Mr. Glover stated there had not been any stability failures to date.

Product on Stability	**Lot**
Levetiracetam Tablets, 750 mg	[redacted]
Levetiracetam Tablets, 500 mg	[redacted]
Liothyronine Sodium Tablets, USP, 5 mcg	[redacted]
Levetiracetam Tablets, 1000 mg	[redacted]
Glipizide Tablets, USP 10 mg	[redacted]
Topiramate Tablets, 50 mg	[redacted]
Ciprofloxacin Tablets, USP 500 mg	[redacted]
Levetiracetam Tablets, 750 mg	[redacted]

I reviewed the finished product testing for the lots where the operators did not follow the appropriate SOP for red screen for each product from [redacted] **(Exhibits 75 – 108)**. I had no objectionable observations.

I asked Mr. Glover if there were any investigations concerning the affected lots other than [redacted]. He stated there were a total of [redacted] investigations concerning these lots. I reviewed and collected copies [redacted] **(Exhibits 109 -113)**. [redacted] covered one tablet weight OOS for lot [redacted] Venlafaxine HCL Tablets, 37.5 mg. [redacted] covered lower than expected but not OOS dissolution data for lot [redacted] Liothyronine Sodium, USP, 5 mcg. [redacted] covered an OOS RSD value for blend uniformity for lot [redacted] Trifluoperazine HCL Tablets, USP 10 mg. [redacted] covered composite assay testing out of Proven Acceptance range, but not OOS for lot [redacted] Levothyroxine Sodium Tablets, USP 25 mcg. [redacted] covered greater than expected, but not OOS results for Dissolution –UV-VIS

testing for lot [redacted] Ketoprofen Extended Release Capsules, 200 mg. I had no objectionable observations.

Mr. Glover stated the firm started phasing the LIMS system into production for capturing the in process physical data test results in [redacted]. The validation of the LIMS system for physical testing in manufacturing was covered during the previous FDA GMP inspection conducted from 11/26/07 – 12/13/07 and there were no objectionable observations. Mr. Glover stated that LIMS was fully implemented in the production area for physical testing in [redacted]. I asked about the user roles in LIMS and the system privileges. Mr. Glover provided a copy of [redacted] "[redacted] LIMS User Account Creation and Maintenance" Issue date [redacted] **(Exhibit 114)**. I reviewed the red screen data provided and found the operator identification for the original reading matched operator identification for the corrected reading in each incident. Mr. Glover indicated that the right click feature was within the operator's user role with in the current software. I reviewed the SOP and had no objectionable observations.

I reviewed [redacted] **(Exhibit 12),** [redacted] **(Exhibit 115)**, and [redacted] **(Exhibit 116)**. I had no objectionable observations.

I asked Mr. Glover how many batches were manufactured, how many dosage units were manufactured, and how many individual physical tests have been performed since the LIMS system was fully implemented in [redacted]. Mr. Glover had the data queried from the system and found there were [redacted] batches of product consisting of [redacted] dosage units manufactured from [redacted]. He stated that there were [redacted] individual physical tests performed and recorded in LIMS during that same period. I asked him to calculate the percentage of individual tests that had improperly handled red screens out of the total. He calculated the percentage and he stated the percentage was [redacted]% of the individual physical tests or data points.

From the data provided by Mr. Glover **(Exhibit 21)**, I calculated the percent of the data from in process physical testing that did not follow the appropriate SOP for red screens for each product from [redacted].

Product	Lot	Red Screens Improperly Handled	Total number of in process physical tests on lot	Percent in process physical testing data not following SOP
Amlodipine Besylate Tablets, 10 mg	[redacted]	1	[redacted]	[redacted]
Verapamil HCL Extended Release Capsules (PM), 100 mg	[redacted]	2	[redacted]	[redacted]
Cetirizine Hydrochloride Tablets, 5 mg	[redacted]	1	[redacted]	[redacted]
Venlafaxine HCL Tablets, 37.5 mg	[redacted]	1	[redacted]	[redacted]
Levetiracetam Tablets, 500 mg	[redacted]	1	[redacted]	[redacted]
Atenolol Tablets, USP, 50 mg	[redacted]	1	[redacted]	[redacted]
Nadolol Tablets, USP, 40 mg	[redacted]	1	[redacted]	[redacted]
Liothyronine Sodium, USP, 5 mcg	[redacted]	1	[redacted]	[redacted]
Carbidopa and Levodopa Tablets, 25/250 mg	[redacted]	1	[redacted]	[redacted]
Verapamil Hydrochloride Extended Release Tablets, USP 240 mg	[redacted]	1	[redacted]	[redacted]
Levetiracetam Tablets, 1000 mg	[redacted]	1	[redacted]	[redacted]
Trifluoperazine HCL Tablets, USP 10 mg	[redacted]	1	[redacted]	[redacted]
Divalproex Sodium Delayed Release Intermediate Pellets	[redacted]	1	[redacted]	[redacted]
Divalproex Sodium Delayed Release Intermediate Pellets	[redacted]	11	[redacted]	[redacted]
Amlodipine Besylate Tablets, 5 mg	[redacted]	1	[redacted]	[redacted]
Glipizide Tablets, USP 10	[redacted]	3	[redacted]	[redacted]

mg				
Amitriptyline Hydrochloride Tablets, USP 150 mg	[redacted]	1	[redacted]	[redacted]
Topiramate Tablets 50 mg	[redacted]	1	[redacted]	[redacted]
Divalproex Sodium Delayed Release Intermediate Pellets	[redacted]	3	[redacted]	[redacted]
Divalproex Sodium ER Tablets, 500 mg	[redacted]	1	[redacted]	[redacted]
Levothyroxine Sodium Tablets, USP 25 mcg	[redacted]	1	[redacted]	[redacted]
Ciprofloxacin Tablets, USP 500 mg	[redacted]	3	[redacted]	[redacted]
Diltiazem HCL Tablets, USP 120 mg	[redacted]	1	[redacted]	[redacted]
Amitriptyline Hydrochloride Tablets, USP 25 mg	[redacted]	1	[redacted]	[redacted]
Levetiracetam Tablets, 750 mg	[redacted]	1	[redacted]	[redacted]
Amlodipine Besylate Tablets, 10 mg	[redacted]	1	[redacted]	[redacted]
Ketoprofen Extended Release Capsules, 200 mg	[redacted]	2	[redacted]	[redacted]
Nitrofurantoin Macrocrystals Intermediate 25mg	[redacted]	1	[redacted]	[redacted]
Nitrofurantoin Macrocrystals Intermediate 25mg	[redacted]	1	[redacted]	[redacted]
Divalproex Sodium ER Tablets 250mg	[redacted]	1	[redacted]	[redacted]
Doxycycline Hyclate Delayed Release Tablets 100mg	[redacted]	1	[redacted]	[redacted]
Lovastatin Tablets, USP 10mg	[redacted]	1	[redacted]	[redacted]

CORRECTIVE AND PREVENTIVE ACTIONS

The firm's Executive Summary outlined the Corrective and Preventive Actions for Investigation [redacted], including:

1) Evaluating the LIMS System to determine if specific tools can be disabled:

Mr. Glover stated the firm was told by [redacted] the manufacturer of LIMS, that the current version does not allow features to be blocked or disabled. Mr. Glover said the firm had worked with [redacted] to develop a patch to disable the right click features. He stated that they had already tested an initial patch and sent it back to [redacted] for improvement. Mr. Glover said [redacted] had sent the revised patch back, Mylan had evaluated it and the firm was initiating the change control process to install the new patch to disable the right click function of the software for revising red screen data.

2) Review and revise associated SOPs as necessary:

Mr. Glover stated the firm had reviewed [redacted] issue date [redacted] **(Exhibit 12),** [redacted] **(Exhibit 114)**, and [redacted] **Exhibit 115)** and that the firm had determined no revisions were necessary.

3) Develop a specific training module for the associated SOPs:

Mr. Glover stated they had developed and conducted the training. He provided copies of the training logs **(Exhibits 10 & 11)**.

4) Investigation [redacted] will be completed and evaluated to provide the final disposition of for lot [redacted] Extended Phenytoin Sodium Capsules, USP.

The firm reviewed the investigation and physical testing data and accepted the lot.

I reviewed the firm's Corrective and Preventive Actions and had no objectionable observations.

INTERVIEWS OF MANUFACTURING EMPLOYEES

I asked for a list of manufacturing employees. I selected [redacted] from this list and interviewed them. I interviewed them each separately in a conference room with no one else present.

I interviewed Mr. [redacted], Assistant Manager, Compressing, Mylan Pharmaceuticals Inc. I asked him if he was aware of the use of the right click feature by operators to clear the red screens prior to the investigation, and he said he was not. He said he did not know that a red screen could be cleared by an operator retesting and entering the corrected data in the system without a Supervisor. He stated that immediately after the investigation started that everyone in the compressing and encapsulation departments were required to attend a meeting. He stated they were told an employee was caught fixing a balance incident without a Supervisor. He stated they were told this can not happen under any circumstances, and that it was a violation of SOPs and GMPs.

I interviewed Mr. [redacted], Department Coordinator, Compressing, Mylan Pharmaceuticals Inc. I asked him if he was aware of the use of the right click feature by operators to clear the red screens prior to the investigation, and he said he was not. He said that immediately following the investigation there were meetings in the cafeteria where they were told they are absolutely not allowed to use the right click function to clear a red screen. He said they were told it never should have happened. He said they were told the firm was working to make it so it can not be done again. He said they discussed what could have happened due to the unauthorized practice and the importance of it not happening again.

I interviewed Mr. [redacted], Tablet Press Operator, Compressing, Mylan Pharmaceuticals Inc. I asked if he had used the right click feature to clear a red screen and he said he had not. He said he did not know it was possible to do it and was surprised when the meeting came about. I asked him what he did if he had a red screen. He said he shut down the machine, and got the Supervisor. He said it was very clear. He said right after the investigation they had meetings in the cafeteria and let everyone in compressing and encapsulation know what was going on. He said they told the workers it was not supposed to happen. He told me they later had training sessions to make sure everyone knew the right procedure.

I asked for a list of operators who had not followed the SOP and not informed the Supervisor prior to correcting the OOS data which triggered the red screen. I interviewed Mr. [redacted], Tablet Press Operator, Compressing, Mylan Pharmaceuticals Inc. in a conference room with no one else present. I asked him if he had ever used the right click feature to clear a red screen event. He said he had. I asked him how he had learned about this function. He said it was a basic knowledge of computers. He right clicked on the mouse and found the function was available. I asked him when he used the function; he said he used it when there was an obvious case of operator or instrument error.

He said he absolutely knew the product was safe. He said he would only do it when it was so far out that he knew it was not the correct data. He said he did not understand it was wrong until they held the meetings in May. I asked him if he had a Supervisor's pass word, he said he did not. I asked him what happened after the company found out that operators were using the right click function to clear red screens. He said the company interviewed him and anyone else who had right clicked. He said in the meeting they let every single employee know what was allowed and what was not. He said it appeared they had changed the LIMS system. He said they had conducted training for all the employees. I asked him if he had tried to see if he could use the right click function since the meetings. He said he had not even looked to see if he could still do it.

MANUFACTURING CODES

The firm's manufacturing code system remains the same as during the firm's previous FDA GMP inspection conducted from 11/26/07 – 12/13/07.

The firm's SAP Enterprise Resource Planning System assigns a batch number depending on the item.

Finished Goods	Same as Bulk Batch Number
Validation Bulks	[redacted]
Manufacturing Bulks	[redacted]
R&D Scale-Up Bulks	[redacted]
Solutions/Intermediates	[redacted]

COMPLAINTS

There were no complaints concerning the products covered during this limited inspection.

RECALL PROCEDURES

There were no recalls for the products covered during this limited inspection. The firm's recall procedure was last covered during the FDAGMP inspection conducted from 11/26/07 – 12/13/07.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

I identified no objectionable conditions.

REFUSALS

I encountered no refusals during this inspection.

GENERAL DISCUSSION WITH MANAGEMENT

On 7/28/09, a close out meeting was held. I met with Ms. Patricia M. Latzo, Senior Vice President Global Quality, Mylan, Inc.; Mr. Kevin A. Kolar, Vice President, North America Quality, Mylan, Inc.; and Mr. Richard D. Glover, Vice President, Quality, Mylan Pharmaceuticals Inc. I stated I had reviewed improperly handled red screen events from the firm's investigation; spot checked data from previous year for red screen events, the firm's investigation, corrective and preventative action and found no evidence of data deletion. I stated I had found that there were deviations from their written Standard Operating Procedures; however they had performed an investigation and implemented corrective and preventative action. I stated that a form FDA 483 "Inspectional Observations" would not be issued.

On 7/30/09, a second close out meeting was held. I met with Ms. Patricia M. Latzo, Senior Vice President Global Quality, Mylan, Inc.; Mr. Kevin A. Kolar, Vice President, North America Quality, Mylan, Inc.; and Mr. Richard D. Glover, Vice President, Quality, Mylan Pharmaceuticals Inc. I stated I had reviewed all [redacted] improperly handled red screen events from [redacted] reviewed the improperly handled red screen event that led to the firm's investigation [redacted], reviewed [redacted] and reviewed the Executive Summary. I confirmed that the firm has a commitment from LabWare the manufacturer of LIMS for a patch that will disable the right click functions of the software. Mr. Glover stated they had tested the patch and submitted comments to [redacted]. [redacted] had revised the patch and Mylan had tested and accepted the software patch. Mr. Glover stated that Mylan was initiating the change control necessary to implement the software patch to disable the right click functions. I confirmed again from Mr. Glover that there were no complaints, recalls or stability failures for the [redacted] lots affected by the [redacted] improperly handled red screens. I stated I had found that there were deviations from their written Standard Operating Procedures; however they had performed an investigation and implemented corrective and preventative action. I stated that no FDA 483 "Inspectional Observations" would be issued, nor did I have objectionable observations to discuss.

I explained that I would write the inspection report and my Supervisor, along with Baltimore District Management, would review the report. I explained that if they agreed that everything was covered properly and if they then endorsed the report, then the inspection would be officially closed, otherwise I would be directed to return. I reemphasized that I did not speak for the agency or the District. I stated that the firm would be officially notified of the inspection conclusion when they receive a copy of the report.

ADDITIONAL INFORMATION

On Saturday 7/25/09, I had a message on my home answering machine from Mr. Kevin A. Kolar, Vice President, North America Quality, Mylan, Inc. stating that he would like to talk to me. I called Mr. Kolar and he stated that Mylan had reason to believe that the Pittsburgh Post Gazette was going to publish an article concerning the firm's quality control and red screen events. He stated he had

already contacted, Ms. Paula J. Bretz, CSO in the Morgantown Resident Post stating that the firm wanted to inform the FDA of the situation and stated that they would be ready if the FDA would find it necessary to follow up on the incidents. I then called CSO Bretz and we discussed the matter. I emailed the BLT-DO DIB and Supervisors regarding the phone conversation. I later called Acting DIB Matthew M. Henciak and discussed the report from Mylan with him. He stated to forward the news article if it were published. Later on 7/25/09, I had another phone message from Mr. Kolar. I returned his call and he stated he had been able to read an advance copy of the article and it contained both true and inaccurate information. He again stated that the firm would be ready on Monday morning for an inspection if the FDA felt it was necessary.

On Sunday 7/26/09, I read the online version of the Pittsburgh Post Gazette and forwarded it to Acting DIB Matthew M. Henciak, SCSO Lori S. Lawless and Drug Preapproval Manager, Brooke Higgins. Later Acting DIB Matthew Henciak called me and discussed a limited inspection at Mylan to start 7/27/09. He said I needed to call BLT-DO Preapproval Manager, CSO Brooke Higgins and discuss the inspection with her further. I called her and it was decided that I would initiate the inspection on 7/27/09, and report my findings midday on Monday 7/27. At that time if CSO Higgins and BLT-DO management thought it was necessary, she would travel and join the inspection on 7/28/09. CSO Higgins did not join the inspection.

All other information regarding this inspection has been included under other headings in this report.

SAMPLES COLLECTED

There were no samples collected.

VOLUNTARY CORRECTIONS

There were no observations during the previous inspection, so there are no voluntary corrections to report.

EXHIBITS COLLECTED

Exhibit 1	**Mylan Pharmaceuticals Inc. Manufacturing Organizational Flow Chart, 7 pages**
Exhibit 2	**Mylan Pharmaceuticals Inc. Quality Unit Organizational Flow Chart, 12 pages**
Exhibit 3	**Mylan Inc. Global/Regional Quality Organizational Flow Chart, 2 pages**
Exhibit 4	**Position Description SVP, Global Quality, Mylan Inc., 3 pages**
Exhibit 5	**Position Description Vice President, NA Quality, Mylan Inc., 2 pages**
Exhibit 6	**Position Description Vice President Quality, Mylan Pharmaceuticals Inc., 2 pages**
Exhibit 7	**Position Description Assistant Manager, Manufacturing, Mylan Pharmaceuticals Inc., 3 pages**

Exhibit 8 **Position Description Department Coordinator, Compressing, Mylan Pharmaceuticals Inc., 2 pages**

Exhibit 9 **Position Description Tablet Press Operator, Compressing, Mylan Pharmaceuticals Inc., 3 pages**

Exhibit 10 **Training Log for "[redacted]", 41 pages**

Exhibit 11 **Training Log for [redacted]", 11 pages**

Exhibit 12 **Mylan [redacted] LIMS Version [redacted] Validation Strategy Document dated [redacted], 22 pages**

Exhibit 13 **LIMS Red Screen Presentation, 12 pages**

Exhibit 14 **[redacted], 7 pages**

Exhibit 15 **[redacted]ylan Pharmaceuticals Inc. Event Notification Form Event PR# 32885, 8 pages**

Exhibit 16 **LIMS screen prints for lot [redacted] Extended Phenytoin Sodium capsules invalidated sample box# [redacted], 4 pages**

Exhibit 17 **LIMS screen prints for lot [redacted] Extended Phenytoin Sodium capsules invalidated sample box# [redacted], 4 pages**

Exhibit 18 **LIMS Screen prints for lot [redacted] Extended Phenytoin Sodium capsules invalidated sample box# [redacted], 7 pages**

Exhibit 19 **LIMS screen prints for lot [redacted]Extended Phenytoin Sodium Capsules, data from improperly handled red screen without supervisor notification, 2 pages**

Exhibit 20 **Mylan Executive Summary Extended Phenytoin Sodium Capsules, USP Lot [redacted] Weight Variation Testing, 4 pages.**

Exhibit 21 **SOP deviation (Red screen) [redacted] spread sheet print out, 1 page**

Exhibit 22 [redacted]

Exhibit 23 [redacted]

Exhibit 24 [redacted]

Exhibit 25 [redacted]

Exhibit 26 [redacted]

Exhibit 27 [redacted]

Exhibit 28 [redacted]

Exhibit 29 [redacted]

Exhibit 30 [redacted]

Exhibit 31 [redacted]

Exhibit 32 [redacted]

Exhibit 33 [redacted]

Exhibit 34 [redacted]

Exhibit 35 [redacted]

Exhibit 36 [redacted]

Exhibit 37 [redacted]

Exhibit 38 [redacted]

Exhibit 39 [redacted]

Exhibit 40 [redacted]

Exhibit 41 [redacted]

Exhibit 42 [redacted]

Exhibit 43 [redacted]

Exhibit 44 [redacted]

Exhibit 45 [redacted]

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Exhibit 47 [redacted]

Exhibit 48 [redacted]

Exhibit 49 [redacted]

Exhibit 50 [redacted]

Exhibit 51 [redacted]

Exhibit 52 [redacted]

Exhibit 53 [redacted]

Exhibit 54 [redacted]

Exhibit 55 [redacted]

Exhibit 56 [redacted]

Exhibit 57 [redacted]

Exhibit 58 [redacted]

Exhibit 59 [redacted]

Exhibit 60 [redacted]

Exhibit 61 [redacted]

Exhibit 62 [redacted]

Exhibit 63 [redacted]

Exhibit 64 [redacted]

Exhibit 65 [redacted]

Exhibit 66 [redacted]

Exhibit 67 [redacted]

Exhibit 68 [redacted]

Exhibit 69 [redacted]

Exhibit 70 [redacted]

Exhibit 71 [redacted]

Exhibit 72 [redacted]

Exhibit 73 [redacted]

Exhibit 74 List: AUDIT-TEXT, 1 page

Exhibit 75 Certificate of Analysis for lot [redacted] Divalproex Sodium Delayed Release Intermediate Pellets, dated [redacted] 1 page

Exhibit 76 Certificate of Analysis for lot [redacted] Divalproex Sodium ER Tablets, 500 mg, dated [redacted], 1 page

Exhibit 77 Certificate of Analysis for lot [redacted] Levothyroxine Sodium Tablets, USP 25 mcg, dated [redacted] 2 pages

Exhibit 78 Certificate of Analysis for lot [redacted] Ciprofloxacin Tablets, USP 500 mg, dated [redacted] 2 pages

Exhibit 79 Certificate of Analysis for lot [redacted] Diltiazem HCL Tablets, USP 120 mg, dated [redacted], 1 page

Exhibit 80 Certificate of Analysis for lot [redacted] Amitriptyline Hydrochloride Tablets, USP 25 mg, dated [redacted], 1 page

Exhibit 81 Certificate of Analysis for lot [redacted] Levetiracetam Tablets, 750 mg, dated [redacted] 1 page

Exhibit 82 Certificate of Analysis for lot [redacted] Amlodipine Besylate Tablets, 10 mg, dated [redacted] 1 page

Exhibit 83 Certificate of Analysis for lot [redacted] Ketoprofen Extended Release Capsules, 200 mg, dated [redacted], 1 page

Exhibit 84 Certificate of Analysis for lot [redacted] Nitrofurantoin Macrocrystals Intermediate 25mg, dated [redacted], 1 page

Exhibit 85 **Certificate of Analysis for lot [redacted] Nitrofurantoin Macrocrystals Intermediate 25mg, dated [redacted], 1 page**

Exhibit 86 **Certificate of Analysis for lo[redacted] Divalproex Sodium ER Tablets 250mg, date[redacted], 1 page**

Exhibit 87 **Certificate of Analysis for lot [redacted] Doxycycline Hyclate Delayed Release Tablets 100mg, dated [redacted], 2 pages**

Exhibit 88 **Certificate of Analysis for lot [redacted] Lovastatin Tablets, USP 10mg, dated [redacted], 2 pages**

Exhibit 89 **Certificate of Analysis for lot [redacted] Extended Phenytoin Sodium Capsules, USP 100 mg dated [redacted], 2 pages**

Exhibit 90 **Certificate of Analysis for lot [redacted] Amlodipine Besylate Tablets, 10 mg, dated [redacted], 2 pages**

Exhibit 91 **Certificate of Analysis for lot [redacted] Levetiracetam Tablets, 750 mg, dated [redacted], 1 page**

Exhibit 92 **Certificate of Analysis for lot [redacted] Verapamil HCL Extended Release Capsules (PM), 100 mg, dated [redacted], 1 page**

Exhibit 93 **Certificate of Analysis for lot [redacted] Cetirizine Hydrochloride Tablets, 5 mg, date[redacted], 2 pages**

Exhibit 94 **Certificate of Analysis for lot [redacted] Venlafaxine HCL Tablets, 37.5 mg, dated [redacted], 1 page**

Exhibit 95 **Certificate of Analysis for lot [redacted] Levetiracetam Tablets, 500 mg, dated [redacted], 1 page**

Exhibit 96 **Certificate of Analysis for lot [redacted] Atenolol Tablets, USP, 50 mg, dated [redacted], 1 page**

Exhibit 97 **Certificate of Analysis for lot [redacted] Nadolol Tablets, USP, 40 mg, dated [redacted], 1 page**

Exhibit 98 **Certificate of Analysis for lot [redacted] Liothyronine Sodium, USP, 5 mcg, dated [redacted], 1 page**

Exhibit 99 **Certificate of Analysis for lot [redacted] Carbidopa and Levodopa Tablets, 25/250 mg, dated [redacted] 2 pages**

Exhibit 100 **Certificate of Analysis for lot [redacted] Verapamil Hydrochloride Extended Release Tablets, USP 240 mg, dated [redacted], 1 page**

Exhibit 101 **Certificate of Analysis for lot [redacted] Levetiracetam Tablets, 1000 mg, dated [redacted], 2 pages**

Exhibit 102 **Certificate of Analysis for lo[redacted] Trifluoperazine HCL Tablets, USP 10 mg, dated [redacted], 1 page**

Exhibit 103 **Certificate of Analysis for lot [redacted] Divalproex Sodium Delayed Release Intermediate Pellets, dated [redacted], 1 page**

Exhibit 104 **Certificate of Analysis for lot [redacted] Divalproex Sodium Delayed Release Intermediate Pellets, dated [redacted], 1 page**

Exhibit 105 **Certificate of Analysis for lot [redacted] Amlodipine Besylate Tablets, 5 mg, dated [redacted], 1 page**

Exhibit 106 **Certificate of Analysis for lot [redacted] Glipizide Tablets, USP 10 mg, dated [redacted], 1 page**

Exhibit 107 **Certificate of Analysis for lot [redacted] Amitriptyline Hydrochloride Tablets, USP 150 mg, dated [redacted], 1 page**

Exhibit 108 **Certificate of Analysis for lot [redacted]1 Topiramate Tablets 50 mg, dated [redacted], 1 page**

Exhibit 109 **Mylan Pharmaceuticals Inc. Investigation Report (IR) Form Investigation [redacted], 3 pages**

Exhibit 110 **Mylan Pharmaceuticals Inc. Analytical Investigation Report [redacted], 12 pages**

Exhibit 111 **Mylan Pharmaceuticals Inc. Analytical Investigation Report [redacted], 12 pages**

Exhibit 112 **Mylan Pharmaceuticals Inc. Analytical Investigation Report [redacted], 4 pages**

Exhibit 113 **Mylan Pharmaceuticals Inc. Analytical Investigation Report [redacted], 8 pages**

Exhibit 114 [redacted], 5 pages

Exhibit 115 [redacted]

Exhibit 116 [redacted]

ATTACHMENTS

Attachment 1 FDA 482 "Notice of Inspection" dated 7/27/09 issued to Mr. Richard D. Glover Vice President Quality, 1 page

Attachment 2 FDA 482 "Notice of Inspection" dated 7/29/09 issued to Mr. Richard D. Glover Vice President Quality, 1 page

Attachment 3 Copy of the article from the Pittsburgh Gazette dated July 26, 2009, 9 pages

Attachment 4 Attachment C OEI Improvement Form

William A. Warnick, Investigator
MGN-RP/BLT-DO