DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue, Bldg 51, Rm 4225 Silver Spring, MD 20993 Phone: (301)-796-3334 Fax: (301)-847-8738 Industry Information: www.fda.gov/oc/industry	01/05-11/2014
	FEI NUMBER 3002807972

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dale Adkisson, Head - Global Quality

FIRM NAME	STREET ADDRESS
Ranbaxy Laboratories Limited	Village Toansa, P.O. Rail Majra
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
District SBS Nagar, Punjab, India 144 533	Active Pharmaceutical Ingredient Manufacturer

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1

Raw materials, intermediates, and finished API analytical results found to be failing specifications or otherwise suspect (e.g. OOT) are retested until acceptable results are obtained. These failing or otherwise suspect results are not reported.

Specifically,

A) Our review of your firm's Chemstore archived database and system audit trail on GC # 06 identified the practice of over-writing electronic raw data files (samples and standards) for ongoing sample sequences until acceptable results are achieved.

Based on this practice, Out-Of-Specification (OOS) investigations are not initiated as required per SOP OP003684, "Handling of Out of Specification (OOS)", and/or Deviation investigations are not initiated as required per SOP OP003440, "Handling of Deviations". We identified numerous such examples during our review of archived data drawn from approximately 5 months of data. The number of such examples of over-writing raw data files until acceptable results are achieved could not be quantified during our inspection due to the large amount of data.

For example:

i) Raw material (b) (4) batch # (b) (4) was analyzed for Chromatographic Purity via GC as follows:

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		Peter E. Baker, Investigator Dipesh Shah, Investigator	01/11/2014

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• First sample injection was performed on 05/06/13 @ 9:25pm and saved as file "MAY_0604." Results for Chromatographic Purity were found to be (b) (4)% (specification = NLT (b) (4)%).
• Second sample injection was performed on 05/06/13 @ 9:52pm and was also saved as file "MAY_0604," by over-writing the previous sample data file. Results for Chromatographic Purity were found to be (b) (4)% (specification = NLT (b) (4)%).
• Third sample injection was performed on 05/06/13 @ 10:18pm and was also saved as file "MAY_0604," by over-writing the previous sample data file. It appears the analyst injected an air blank, as no peaks were found to elude.

As a result, the analyst and laboratory supervisor invalidated the sample sequence on 05/06/13 due to "No peak observed in sample run," and the two failing sample results were not reported. No OOS investigation was initiated for these failing results.

The sample sequence was re-run on 05/07/13, and results were reported as (b) (4)%.

ii) Finished API (b) (4) batch # (b) (4) was analyzed for Residual (b) (4) (b) (4) via GC as follows:

• First injection for the (b) (4) standard was performed on 05/26/13 @ 12:51pm and saved as file "MAY_2610." The result for the (b) (4) ratio was found to be (b) (4).
• Second injection for the (b) (4) standard was performed on 05/26/13 @ 1:28pm and was also saved as file "MAY_2610," by over-writing the previous standard data file. The result for the (b) (4) ratio was found to be (b) (4)

The original (b) (4) standard result of (b) (4), which was not reported, is significantly different than the first five system suitability injections (~(b) (4), and causes:

• the system suitability to fail the requirement of NMT (b) (4)% RSD, and
• a significant change in the final API Residual (b) (4) content calculated result for batch # (b) (4)

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iii) Finished API (b) (4) batches # (b) (4) and # (b) (4) were analyzed for Residual (b) (4) via GC as follows:

• First injection for system suitability injection #6 was performed on 11/16/13 @ 12:32am and saved as file "NOV_1507." The result for the (b) (4) ratio was found to be (b) (4)
• Second (b) (4) for system suitability injection #6 was performed on 11/16/13 @ 1:09am and was also saved as file "NOV_1507," by over-writing the previous standard data file. The result for the (b) (4) ratio was found to be (b) (4)

The original system suitability injection #6 result of (b) (4), which was not reported, is significantly different than the first five system suitability injections ((b) (4), and causes a significant change in the:

• %RSD calculation for system suitability, and
• the final API Residual (b) (4) content calculated result for batch #s (b) (4) and (b) (4)

iv) Raw material (b) (4) batch # (b) (4) was analyzed for Chromatographic Purity via GC as follows:

• First sample injection was performed on 07/27/13 @ 2:05am and saved as file "JULY_2703."
• Second sample injection was performed on 07/27/13 @ 2:20am and was also saved as file "JULY_2703," by over-writing the previous data file.

The original sample result (over-written and not reported) contains a significant (b) (4) impurity peak at retention time (b) (4) minutes, which when calculated ((b) (4)%), appears to be at the specification limit of NMT (b) (4)%. The second injection found a (b) (4) impurity result of (b) (4)%, and the original (over-written) result of (b) (4)% was not reported.

v) Intermediate API (b) (4) batch # (b) (4) was analyzed for Residual Solvent via GC as follows:

• First sample injection was performed on 12/10/12 @ 12:28pm and saved as file "FEB_1006." The result for (b) (4) content was found to be (b) (4)%.

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• Second sample injection was performed on 12/10/12 @ 12:59pm and was also saved as file "FEB_1006," by over-writing the previous standard data file. The result for (b) (4) content was found to be (b) (4)%.

This significant change in (b) (4) content alters the result of your other routine test method(s) which use this (b) (4) percentage value as a critical calculation input.

vi) Raw material (b) (4) batch # (b) (4) was analyzed for Enantiomeric Purity via GC as follows:

• First sample injection was performed on 05/05/13 @ 7:20am and saved as file "MAY_0503."
• Second sample injection was performed on 05/05/13 @ 7:55am and was also saved as file "MAY_0503," by over-writing the previous data file.

The original sample result, which appears to have a difference in the peak profile (specifically tailing (poor resolution) in the main (b) (4) peak), was not reported.

B) During our inspection of the QC analytical laboratory on 01/05/14, we identified the presence of a Karl Fischer results printout dated 01/02/14 along with the analytical balance printout also dated 01/02/14 for the raw material (b) (4) batch # (b) (4) Our review found the results of the water content to be (b) (4)%, vs. a specification range of (b) (4)% to (b) (4)% listed in the specification document #AS0028969.

We requested the QC data package for this batch, and found the reported results had been collected on 01/03/14 with the result listed as "water not detected." Our review of the instrument logbook for this Karl Fischer #10101915 found that the testing performed on 01/02/14 had not been recorded.

OBSERVATION 2

Samples are not analyzed according to established laboratory test method procedures.

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Specifically, our review of your firm's Chemstore archived database and system audit trail on GC # 06 identified the practice of performing single manual injections of what appear to be sample aliquots prior to the official sample sequences. Our review of archived data drawn from approximately 5 months of data identified numerous such examples. The number of such examples could not be quantified during our inspection due to the large amount of data. There are no written procedures established to describe the practice of performing these single manual sample injections, and the results are not reported.

These injections were each found titled as "DEFAULTB" and stored in the "Default" data folder. We identified significant chromatographic profile differences when we compared these single manual injections of sample aliquots to the official, reported data. No explanation could be provided regarding these differences due to the lack of documentation.

For example:

A) A total of five "DEFAULTB" injections of what appear to be sample aliquots for raw material (b) (4) (b) (4) batch # (b) (4) (drum #30) were performed on 05/04/13 from 1:17am to 3:24am, prior to the official/reported sample sequence for Chromatographic Purity via GC initiated at 4:28am. The five "DEFAULTB" injection results were not reported. The peak profiles and purity results for these five injections were found to be significantly different than that reported in the official QC data package. For example:

• Injection #3 of 5, performed at 2:08am on 05/04/13 was found to fail the specification limits for:

o Total Impurities (b) (4)% vs. limit of (b) (4)%)
o (b) (4) Content ((b) (4)% vs. limit of less than (b) (4)%)
o Any other individual impurity (b) (4)% vs. limit of less than (b) (4)%)

B) A total of two "DEFAULTB" injections of what appear to be sample aliquots for finished API (b) (4) USP batch # (b) (4) were performed on 07/08/13 from 4:19pm to 4:50pm for Residual Solvents via GC, following an invalidated data set completed on 07/08/13 @ 2:14am and prior to the retesting performed on 07/10/13. Notably, the known impurity "(b) (4)" was detected in the second "DEFAULTB" injection on 07/08/13, which was not detected in any of the results reported in the official QC data package.

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OBSERVATION 3

Appropriate controls are not established over computerized systems.

THIS IS A REPEAT OBSERVATION FROM THE PREVIOUS FDA INSPECTION IN 12/2012

Specifically, the stand-alone computerized system controlling GC #6 does not have sufficient controls to prevent unauthorized access to, changes to, or omission of data files and folders. During our review of the Chemstation system audit trail, we found that raw data files related to standard and sample injections can be deleted and all evidence of testing removed, as demonstrated by the lack of raw data files present in the electronic Chemstore data archives.

For example:

A) Our review of the audit trail for the month of 01/2011 identified at least one injection performed for what appears to be related to the OOS investigation of (b) (4) batch # (b) (4) Residual (b) (4) via GC on 01/06/11. Our review of the electronic data archives found that this injection had not been retained.

B) Our review of the audit trail for the month of 08/2013 identified sample injections performed for (b) (4) (b) (4) batch # (b) (4) Residual Solvent via GC on 08/27/13. Our review of the electronic data archives found that these injections had not been retained.

OBSERVATION 4

Records are not completed contemporaneously.

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Specifically,

A) During our inspection of the QC analytical laboratory on 01/05/14, we observed one analyst back-date the working standard issuance and destruction logbook for (b) (4) USP/EP batch # (b) (4) and # (b) (4) This analyst was observed to sign and date the record "04-JAN-2014." We immediately questioned this analyst regarding the reason for back-dating this record, who responded that he had only entered "2014," despite our visual observation of him entering a signature and full date entry a few moments earlier.

B) During our inspection of the QC analytical laboratory on 01/05/14, we identified a total of six partially completed "Employee Certification" forms attached to QC data packages located throughout the facility. According to SOP OP008930 "Certification from employees involved in GMP, GCP, GLP and or R&D activities supporting US FDA regulatory submissions", these forms are used "to comply with the Consent Decree of Permanent Injunction" with "USFDA" regarding the "Data Integrity Management, Paragraph A," and include the signature and date of the analyst certifying that:

- "I performed the activities recorded for the above stage as having been performed by me"
- "I performed the activities recorded for the above stage accurately and completely to the best of my knowledge"

According to section 6.6.2 of the SOP, these forms are to be completed at the time the test method is performed and in chronological order. We found these forms to be partially completed, with what appeared to be spaces created for entry of data in chronological order and back-filling/back dating of the records.

For example, the Employee Certification form found attached to the QC data package for (b) (4) batch # (b) (4) was found to have entries in line numbers 2 and 5 only, signed on 11/22/13 and 11/23/13, respectively, which appeared to allow back-filling/back-dating of the remaining analyst signatures and dates in chronological order. Our review of the QC data package found that the blank space created in line number 1 appeared to be created for back-filling/back-dating of information for testing performed on 11/21/13, while the blank spaces created in line numbers 3 and 4 appeared to be created for back-filling/back-dating of information for testing performed on 11/22/13.

C) During our inspection of the QC analytical laboratory on 01/05/14, we identified the presence of numerous

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sticky notes attached to QC data packages being stored throughout the raw material, in-process, and finished product testing areas. These sticky notes were found to contain instructions for corrections to be made to the raw data. We found that these corrections had not yet been made despite the "Checked By" field already being signed/dated by the second analyst.

For example, one sticky note was identified on 01/05/14 containing instructions to change the name of a buffer used in the sample preparation. However, the record had been signed/dated as reviewed by the second analyst in the "Checked By" field on 01/02/14.

D) During our review of the QC data package for (b) (4) batch # (b) (4) on 01/05/14, we found that the results for the Karl Fischer water content testing had been generated on 01/02/14 and 01/03/14. However, our review of the "Analytical Raw Data Sheet" found that the sample preparation and testing raw data (e.g. solvent batch # used and responsible analyst) had not yet been entered.

Notably, our review of multiple printed SOP's found throughout the facility found what appeared to be raw data (e.g. weights, dilution factors, etc.) written throughout the documents.

OBSERVATION 5

Laboratory samples are not adequately controlled to prevent mix-ups.

Specifically,

A) During our inspection of the QC analytical laboratory on 01/05/14, we identified two HPLC vials labeled as what appeared to be "2" and "3" within the sample receiving freezer #10105211. Upon return to the laboratory on 01/06/14, we found that these two vials had been discarded, despite our inspectional request the previous day to determine the identity/content of the vials. During the course of our inspection, the identity/fate of these HPLC vials could not be determined.

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B) During our inspection of the process development laboratory, which provides GMP testing support to the manufacturing department, we identified the presence of three samples of (b) (4) finished API batch numbers (b) (4) and (b) (4) within the drawer labeled "Blank Paper" under a stack of blank paper at the bottom of the drawer. No explanation was provided regarding the reason for storing these samples in the drawer designated for "Blank Paper."

C) During our inspection of the working standard storage (2 – 8C) refrigerator #10105207, we identified the presence of one container labeled as "(-) – (b) (4) for stability study" with the batch number listed as "(b) (4)". No justification and/or documentation regarding this uncontrolled container labeled as "for stability study" were provided, considering this same batch has been included in the official stability program for (-) – (b) (4) described in protocol SP-044-13 to be stored at 2 – 8C.

D) During our review of the "Sample Receipt Record" logbook for incoming receiving of samples within the GC Laboratory on 01/06/14, we requested visual examination two working standard samples ((b) (4) batch # (b) (4) and # (b) (4)) listed as received on 01/02/14 and recorded as in-stock. During the course of our inspection, the location and/or fate of these two working standards could not be determined.

OBSERVATION 6

Adequate laboratory facilities are not maintained.

Specifically,

A) Our inspection of the QC analytical and microbiology laboratories found the facility to be in significant disrepair. Laboratory windows within the instrumentation (e.g. HPLC) rooms were found to be un-closeable, Too Numerous To Count (TNTC) flies were observed throughout the sample preparation room, and laboratory reagent/ equipment/documentation storage cabinets were found to be broken and un-closable.

B) During our inspection of the QC analytical laboratory on 01/05/14, we found a pool of water directly under the

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working standard storage refrigerator #10100204 maintained at 2 – 8 °C. Upon opening this refrigerator, a significant buildup of melting ice was observed, causing a pool of water to form at the base of the internal cavity where working standard sample containers were found to be stored.

THIS OBSERVATION WAS DISCUSSED WITH MANAGEMENT DURING THE PREVIOUS FDA INSPECTION CLOSE-OUT MEETING IN 12/2012.

OBSERVATION 7

Records regarding the maintenance of manufacturing equipment are not completed.

Specifically, during our inspection of the Unit (b)(4) manufacturing block on 01/08/14, we reviewed the "Maintenance Work Permit" records currently stored in the documentation room, and found that 43 of approximately 55 records reviewed were not signed by the responsible employee demonstrating that the work had been "completed" and a "satisfactory job done", as required per section 6.3.7 of SOP OP003748, "Maintenance of building and equipment".

OBSERVATION 8

Analytical instruments are not calibrated, qualified, or maintained appropriately.

Specifically, analytical instrumentation located within your firm's process development laboratory, which provides GMP testing support to the manufacturing department, has not been:

1) qualified
2) calibrated at regular intervals, and
3) maintained at regular intervals.

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This includes, but is not limited to, the pH meter, Karl Fischer, and analytical balance located within this laboratory facility.

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