

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 10903 New Hampshire Ave, Bldg 51, Rm 4225 Silver Springs, MD 20993 (301) 796-3334 Fax: (301) 847-8738 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 09/11/2012 - 09/26/2012 FEI NUMBER 3002807979
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Naresh Gaur, Plant Head

FIRM NAME Ranbaxy Laboratories, Ltd.	STREET ADDRESS SEZ Unit 1, Plot No. A-41 Industrial Area Phase VIII, SAS Nagar
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CITY, STATE, ZIP CODE, COUNTRY Mohali, Punjab 160 071, India	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer
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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:

QUALITY SYSTEM

OBSERVATION 1

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

Specifically, investigations conducted by your firm from January 2011 through present do not always determine a root cause, do not have adequate data to support the root cause, and/or lack adequate corrective actions and/or follow-up. For example:

a) Deviation 44254 (initiated 05-Jul-2012) involves (b)(4) tablets (b)(4) mg, Batch# (b)(4) where a tablet was found to be out of the specified weight limit during an in process control (IPC) check. This out of limit was not detected during production (no deviation noted in the batch record), only on later review of the executed batch. No investigation was made to find root cause, to develop actions to be taken to prevent this type of deviation from recurring, and no documented follow-up was conducted.

b) OOS 13599 (initiated 08-Jul-2011) concluded that the root cause for the dissolution failure of (b)(4) Capsules (b)(4) mg, batch (b)(4) was higher alkaline pH in sample collection tubes. The pH of the 3 of 6 dissolution samples that failed to meet dissolution criteria was not evaluated, nor was there a route established through the investigation to support the presence of the extremely high pH (b)(4) (b)(4) necessary to degrade the active ingredient to obtain low dissolution results. The OOS data was invalidated and the sample was retested.

c) Deviation 48594 (initiated 11-Aug-2012) concluded that a black fiber embedded in a (b)(4) tablet of (b)(4) Tablets (b)(4) mg, Batch (b)(4) was likely either white (b)(4) tape remnants on the nozzle head of the (b)(4) machine or a hair from an employee's arm that could be exposed on loading the machine. The firm did not conduct any analysis of the fiber to support these root causes. Further, a plan to evaluate whether the corrective actions of trimming the (b)(4) tape and implementing longer gloves for employees were effective was not established.

d) Investigation 36683 (initiated 25-Apr-2012) concluded that an out of limit hardness in-process check for (b)(4) mg Tablets Batch (b)(4), was due to a single (b)(4) punch jamming during operation which resulted in higher hardness.

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The investigation revealed that the operator had manually adjusted the compression force on the tablet compression machine prior to the failing IPC test point. The effect of this change was not evaluated. The affected product was re-incorporated into the acceptable portion of the batch upon obtaining passing dissolution results.

e) Investigation 45035 (completed 11-Aug-2012) concluded that the rejection (due to appearance) of the 3 process validation batches for (b)(4) mg Tablets Batches (b)(4), & (b)(4), was due to variations in hardness due to compression on the (b)(4) compression machine. The investigation did not extend to the equipment qualification of the (b)(4) compression machine to determine if the machine had been evaluated for use with this larger ((b)(4) g weight) tablet. The equipment qualification for this machine occurred with (b)(4) mg (- (b)(4) mg tablet weight).



f) Deviation 42470 (initiated 20-Jun-2012) concerning (b)(4) tablets ((b)(4) mg; batch (b)(4)) with (b)(4) spots, logo erosion, and abrasion on the surfaces concluded that improper manual distribution of (b)(4) was responsible for the (b)(4) spots and that (b)(4) of the tablets during (b)(4) likely caused the logo erosion. Actions taken to correct and prevent this deviation including (b)(4) of the (b)(4) during distribution and monitoring the (b)(4) thought responsible for the (b)(4) tablets were not verified as effective, and no documented follow-up was found in the investigation to ensure this type of deviation will not be repeated with this or other drugs.

g) OOS 44654 (initiated 09-Jul-2012) concluded that the root cause for the detection of (b)(4) in the Related Substance analysis for (b)(4) and (b)(4) ((b)(4), (b)(4) mg, batch (b)(4)) was use of dirty glassware by the analyst. The investigation did not reveal the source of the uncleaned glassware. Further, the amount of (b)(4) detected was on the magnitude of the amount of active ingredients, (b)(4) and (b)(4). The OOS data was invalidated and the sample was retested.

h) OOS 33839 (initiated 27-Mar-2012) concluded that the root cause for the Total Organic Carbon (TOC) excursion of two water monitoring points was due to sample exposure in vial or undue contamination. The investigation centered on the effect the exposure of the sample vials (sample kept in vials without caps) had on TOC. Interviews with the analyst did not indicate that the caps had been left off or improperly affixed to support this root cause. The OOS data was invalidated and new water samples were collected and analyzed.

i) Deviation 37001, initiated 4/27/12 for (b)(4) mg Tablets Batch # (b)(4) in response to the presence of black spots observed in tablets during Tablet Compression. The investigation did not include chemical analysis of the tablet (b)(4) or contaminated tablets to support the absence of contamination in the (b)(4) and the root cause, which was determined to have originated from oil in the compression machine. In addition, no documented follow-up was conducted to ensure the effectiveness of actions taken to prevent a recurrence.

j) Deviation 17217, initiated 8/31/11 for (b)(4) mg Capsules Batch # (b)(4) in response to the presence of dents on the capsules observed during the capsulation process. The investigation concluded that the (b)(4) capsule supplier did not meet physical quality criteria, requiring adjustments to the capsule filling machine. No documented follow-up was conducted to ensure the effectiveness of actions taken to prevent a recurrence.

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OBSERVATION 2

Investigations of an unexplained discrepancy did not extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy.

Specifically, your firm did not extend its investigations to other batches of (b)(4) mg Tablets and other drug products when conclusions were made that the potential for the packaging line failure existed on all (b)(4) of the firm's identical packaging lines for all products manufactured by the firm since the firm began operations in March 2012. Investigation # 45672, initiated 7/17/12, and Investigation # 49120, initiated 8/17/12, were each in response to Market Complaints that reported that unlabeled bottles of (b)(4) mg Tablets, Batch # (b)(4) and # (b)(4), respectively, had been received at each of two pharmacies. The firm's investigations did not include a discussion of other batches and other products that have already been distributed.

OBSERVATION 3

An (b)(4) -Field Alert Report was not submitted within three working days of receipt of information concerning a failure of one or more distributed batches of a drug to meet the specifications established for it in the application.

Specifically, no field alert reports were submitted in response to information received by the firm in two Market Complaints, each of which reported that one or more bottles of (b)(4) mg Tablets contained no primary label on the bottle.



- a) Complaint # E/MCV/12/002, received 7/17/12, reported that one unlabeled bottle was received by the pharmacy in a (b)(4) package of (b)(4) bottles of (b)(4) mg Tablets # (b)(4) count, Batch # (b)(4).
- b) Complaint # E/MCV/12/006, received 8/16/12, reported that four unlabeled bottles were received by the pharmacy in a shipment of (b)(4) bottles packaged in (b)(4) packs of (b)(4) bottles of (b)(4) mg Tablets # (b)(4) count, Batch # (b)(4).

PRODUCTION AND PROCESS SYSTEM

OBSERVATION 4

Control procedures are not established which monitor the output and validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically, your firm does not always establish adequate process controls and/or product specifications. For example,

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- a) In the manufacture of (b)(4) mg Tablets, Batch # (b)(4), manufactured 5/08/12, a target process parameter for Compression Machine Speed was not established, however (b)(4) rpm is indicated as the validated range, which may be adjusted by the operator throughout the compression process. Process Validation for (b)(4) mg did not evaluate the impact of all permutations available from operation of all parameters such as tablet hardness and thickness that are allowed to be operated at ranges. Review of several batch records indicate that it is common practice to utilize (b)(4) compression speeds at (b)(4) of compression followed by (b)(4) compression speeds at the (b)(4) of compression. However, there were instances of having to (b)(4) compression speed (b)(4) mg, batch (b)(4)) during the course of compression due to sticking punches.
- b) There is no data to support that an adequate seal is consistently attained in the final packaging of solid oral dosage forms, including (b)(4) and (b)(4) Tablets, in that the validation does not fully include establishment of process specifications in the (b)(4) sealing process (to include bottle height along with conveyor speed and power). Additionally, devices responsible to ensure consistent speed and power are not calibrated.
- c) SOP OP006449 "Deviation Management" (v. 1.0 effective 12-Aug-11) does not provide guidance for evaluation and usage decisions on product that has failed IPC testing. Acceptance/sampling/testing of failed IPC product is handled on a case-by-case basis which allows for non-uniform practices in treatment of failed product and scientific rationale in the treatment of failed product is not always evident.
- d) SOP OP003195 "Inprocess checks during processing of batch" (v. 4.0 effective 13-Jun-2012) does not require the operator to perform IPC after changing compression force to evaluate the impact of change on key product attributes. Compression force is routinely adjusted on the (b)(4) compression machine (used in the manufacture of (b)(4) mg process validation batches) to change hardness. Changes to the compression force are not noted in the batch record nor is IPC performed after adjusting this value.
- e) SOP OP003290 "Procedure for operation and cleaning of tablet compression machine" (v. 4.0 effective 01-Jun-2012) does not provide the operator guidance in using the manual adjustment knob on the (b)(4) compression machine to adjust hardness during the course of compression. This knob is routinely adjusted during the course of compression to affect hardness.
- f) For (b)(4) solution used in (b)(4) Tab production, directions for (b)(4) are (b)(4) (b)(4). These procedures allow the operator to make a decision on (b)(4) speed, time, and end point of (b)(4). Similarly, for preparation of (b)(4) in the (b)(4) step for (b)(4) Tabs it reads, (b)(4) (b)(4) " allowing the operator to determine parameters of (b)(4).
- g) In (b)(4) tablet production, (b)(4) speed is not fully controlled by written instructions to ensure proper (b)(4) of tablets. (b)(4) speed ranges given in the batch record, if followed, may cause variability in the characteristics of the in-process material and the drug product. (b)(4) speed ranges are given as (b)(4) (b)(4), but if set at (b)(4) at the (b)(4) of (b)(4), proper (b)(4) will not occur.

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h) The (b)(4) step (b)(4) Tabs (b)(4) rate has exaggerated ranges ((b)(4),(b)(4)) in the batch record that, if followed, could cause variability in the characteristics of the in-process material and the drug product. Actual working ranges were observed to be from (b)(4),(b)(4).

OBSERVATION 5

Written production and process control procedures are not followed in the execution of production and process control functions.

Specifically, your firm does not always follow written procedures for the tablet compression process in the manufacture of solid oral dosage forms such as (b)(4) and (b)(4) Tablets in that the tablet compression machine speed is varied throughout the compression process. For example, in the manufacture of:

- a) (b)(4) mg Tablets, Batch # (b)(4), the established process parameter for machine speed is (b)(4) rpm; however, according to In-Process Control Records, the machine speed was (b)(4) rpm at the time of the (b)(4) and QA checks. The machine speed was then varied at (b)(4) rpm, (b)(4) rpm, (b)(4) rpm, and (b)(4) rpm throughout the compression process.
- b) (b)(4) mg Tablets, Batch # (b)(4), the established process parameter for machine speed is (b)(4) rpm; however, according to In-Process Control Records, the machine speed was (b)(4) at (b)(4) rpm. During the batch it was (b)(4) to (b)(4) rpm where the compression process completed. Further, upon changing the compression speed from (b)(4) rpm to (b)(4) rpm, the IPC performed after the speed change was incomplete as only tablet weight was evaluated. SOP OP003195 specifies a full IPC to be performed when the compression speed is changed.

OBSERVATION 6

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically,

- a) Written procedures (SOP OP003411 v 5.0 effective 16-Aug-2012) for cleaning non-dedicated equipment do not adequately define methods, equipment and parameters (such as volume of water, time, pressure) used to ensure controlled, effective and consistent/reproducible cleaning results. There is no data to support that presumed hard to clean areas, where swab sampling occurs, were scientifically determined. Visible residual material (previous lot (b)(4) Tablets (b)(4) mg, batch # (b)(4)) was observed during this inspection in the air inlet and exhaust areas of cleaned and company production management checked/inspected (b)(4) machine (MPDGAC01) process equipment located in manufacturing room (b)(4).

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b) There is not always sufficient data to support manufacturing steps not adding variability into the manufacturing process. For example,

i) The batch record for (b)(4) process for (b)(4) (all strengths) indicates a target range (b)(4) for weight addition to determine the (b)(4) endpoint. Review of several batch records revealed that this lower end of the range ((b)(4) %) is never utilized as the stopping point as the operator "knows" that there will be (b)(4) during (b)(4) of the (b)(4) product that could take the product out of the specified range. Instead, several within specification end points are passed with typical final endpoint values of (b)(4) (b)(4) %.

ii) The batch record for (b)(4) of the (b)(4) for (b)(4) mg (step (b)(4)) instructs the operator to stop the (b)(4) process once certain parameters are met including product temperature (b)(4) C and (b)(4) (NMT (b)(4) %). Operators routinely continue the (b)(4) process after these parameters are met as they "know" it to be necessary to continue the (b)(4) process to obtain the optimum product for the next manufacturing step.

FACILITIES AND EQUIPMENT

OBSERVATION 7

Routine checking of mechanical equipment is not performed according to a written program designed to assure proper performance.

Specifically, raw and in-process material storage areas may not meet the established requirements in that studies to determine the optimal environmental monitoring locations for several storage/warehouse areas including Raw Materials Warehouse 1, Raw Materials Warehouse 2, and In-process Storage 2 were found to be deficient as follows:

- a) There is no adequate rationale for the placement of the temperature and relative humidity monitoring device in Raw Material Warehouse 1, in that the permanent monitoring location is different from worst case location determined through temperature mapping study, MV-P/TM002-02 12-Sep-2011, and is also reportedly not a likely storage area as it is next to the emergency door.
- b) There is inadequate data to support the placement of the temperature and relative humidity monitoring device in Raw Material Warehouse 2 in that there was missing data for several locations and scientific rationale was not utilized in accepting the study with the missing data, nor was the impact of the missing data assessed during the temperature mapping study performed under protocol MV-P/TM008-00, summarized in report MV-R/TM-008-00/006 15-Sep-2012.
- c) There is no adequate justification for the placement of the temperature and relative humidity monitoring device in In-Process Storage 2 in that excursions from the pre-defined acceptance criteria were experienced and were not handled in accordance to Protocol MV-P/TM018-00 (20-Jan-2011), which concluded that the room was uniform and that monitoring

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could occur at any location.

OBSERVATION 8

Washing and toilet facilities lack hot and cold water.

Specifically, during the course of the inspection the toilet facility adjoining change room MWS04 of the Raw Material Storage area did not have running water for hand washing and toilet flushing. The water supply was reportedly turned off during maintenance and inadvertently left off. Additionally, there are no procedures to direct employees to wash hands with soap and water after toilet use and prior to gowning, and no adequate facilities and procedures for employees to wash their feet prior to donning factory-issued work sandals which expose bare feet, and are authorized footwear in the unclassified areas of the manufacturing facility per SOP OP003304 (v. 4.0 effective 11-Jun-2012) "Gowning and Degowning procedure for entry and exit in production/warehouse area".

OBSERVATION 9

Adequate exhaust systems or other systems to control contaminants are lacking in areas where air contamination occurs during production.

Specifically, the (b)(4) air filter equipment, Air Displacement Unit (ADU), used in tablet bottling operations for (b)(4) tablets does not contain adequate filters (e.g., HEPA) to prevent the release and recirculation of dust created during the bottling operation, whereby the potential for cross-contamination may exist.

LABORATORY SYSTEM

OBSERVATION 10

Established test procedures are not documented at the time of performance.

Specifically, the analytical green sheets used by analysts to record the testing of various materials do not contain sufficient information to verify actual reagents and apparatus used in analyses. For example, the green sheet for (b)(4) and other raw materials such as (b)(4) do not contain complete information on reagents and solutions used in physical chemistry tests such as Heavy Metals, (b)(4) from (b)(4), (b)(4) from (b)(4), (b)(4) - reducing substances, (b)(4) and (b)(4) and other physical chemistry tests. Microbiology green sheets for products such (b)(4) finished product do not contain complete information on how analyses are performed.

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Further, some green sheets contain pre-printed instructions which do not always contain relevant information on concentrations of reagents for certain analyses.

MATERIALS SYSTEM

OBSERVATION 11

Written procedures are lacking which describe in sufficient detail the testing, approval, and rejection of components.

Specifically, the approval of (b)(4) does not include a review of the monitoring system inputs to ensure the system is consistently functioning as intended. For example, in the manufacture of (b)(4), used in cleaning equipment and as a component in the (b)(4) and (b)(4) used in the manufacture of solid oral dosage forms such as (b)(4) and (b)(4) Tablets, your firm does not adequately monitor established operating parameters such as flow rates, water pressure and (b)(4) power for the (b)(4), to ensure that appropriate operating conditions are met.

Additionally, the (b)(4) well (water source) located outdoors is not fully protected from entry of potentially contaminated water and filth such as rainwater runoff. There is no schedule for sanitization or replacement of the (b)(4) Filter (b)(4), as this (b)(4) containing (b)(4) has not been sanitized since installment in 2008. Raw water tanks have air vents not fully protected and ill-fitting manhole covers that may allow access of pests and other contaminants.

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