DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Ave. Jamaica, NY 11433 (718) 340-7000 Fax:(718) 662-5661	07/13/2009 - 08/12/2009* FEI NUMBER 3001236657

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Robert Patton, Vice President & General Manager

FIRM NAME	STREET ADDRESS
Ohm Laboratories, Inc.	34 West Fulton Street
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Gloversville, NY 112078	Rx Drug Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

POST-MARKETING REPORTS

OBSERVATION 1

An annual report did not include information about the quantity of the drug product distributed under the approved application, including that distributed to distributors.

Specifically, your recently filed Annual Report for ANDA 78-448, Ranitidine HCl Solution USP, 15 mg/mL, dated February 10, 2009 covering the review period of December 13, 2007 - December 12, 2008.

You failed to include in this report the distribution data on the subject application of all lots manufactured at your site and distributed from your site. Third paragraph of this Annual Product report declared that "no product has not been manufactured or distributed during the reporting period"; although according to the Packaging Line Log [redacted] and Filling Room [redacted] Log, the following lots of the subject drug product were manufactured during the mentioned review period: Lot #'s 1860614, 1860616, 1861527, 1901358, 1902801, 1901850, 1902802, 1902803 and 1902804. Furthermore, lot #[redacted] was rejected because the operators failed to add the require amount of the active pharmaceutical ingredient during compounding, even though the batch manufacturing record ascertain the addition of the material by an operator and to be verified by the Plant Manager. (b)(4)

In addition, there was a batch size increase from [redacted] Liters (exhibit batch #5750601) to [redacted] (commercial size). According to your Master Batch Manufacturing Issuance Log, in 2008 it was issued the following BMR's to production (total of 10): (b)(4) (b)(6)

Date BMR issued	Batch	Batch Size (L)	Mfg. Date	Exp. Date	MBR / PBR No.	Issued By	Date of Return to QA	Received by	Remarks	Retain Sample data available (yes or no)
01/28/08	[redacted] *	[redacted]	01/2008	12/2009	[redacted]	[redacted]	Log Left in blank	Log Left in blank	*	No
01/29/08	1860614	[redacted]	01/2008	12/2009		[redacted]	02/21/08	[redacted] ***	*Prospective Validation*	Yes
01/31/08	1860616	[redacted]	01/2008	12/2009		[redacted]	02/21/08	[redacted] ***		Yes
02/01/08	1861527	[redacted]	01/2008	12/2009		[redacted]	02/21/08	[redacted] ***		Yes

(b)(4)

SEE REVERSE OF THIS PAGE

DATE ISSUED
08/12/2009

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Ave. Jamaica, NY 11433 (718) 340-7000 Fax:(718) 662-5661	07/13/2009 - 08/12/2009* FEI NUMBER 3001236657

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Robert Patton, Vice President & General Manager

FIRM NAME	STREET ADDRESS
Ohm Laboratories, Inc.	34 West Fulton Street
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Gloversville, NY 112078	Rx Drug Manufacturer

		(b)(4)				(b)(4)		(b)(4)	
05/13/08	1901358 **	[redacted]	05/2008	04/2010		[redacted]	07/10/08	[redacted] ***	Yes
05/15/08	1902801 ** & ***	[redacted]	05/2008	04/2010		[redacted]	07/10/08	[redacted] Deviation [redacted]	Yes
05/19/08	1901850 **	[redacted]	05/2008	04/2010		[redacted]	07/10/08	[redacted]	Yes
05/19/08	1902802 **	[redacted]	05/2008	04/2010		[redacted]	07/10/08	[redacted] ** Deviation [redacted]	Yes
05/27/08	1902803 **	[redacted]	05/2008	04/2010		[redacted]	07/10/08	[redacted]	Yes
05/27/08	1902804 **	[redacted]	05/2008	04/2010		[redacted]	07/10/08	[redacted]	Yes

(b)(4) * Batch was rejected due to alleged "weighing problems." Only [redacted] kg instead of [redacted] kg of the API was used in the formulation ([redacted] containers out of [redacted]. However, there is no evidence that your personnel ever weighed the [redacted] container. Furthermore, the operator and Plant Manager signed the BMR as performing and verifying that particular operation of adding the material. Failure Investigation Report was initiated by the Plant Manager and training to personnel was provided by him as well, even thought he was involved in the incident/failure. There are two more lots of different drug products rejected because of weighing issue and/or even starting the manufacturing operation without having all required materials.

(b)(4) ** You released and distributed lots with questionable investigation related to floating particles of fiber and cardboard inside the product. Deviation No. [redacted], completed on 07/07/08.

(b)(4) *** The floating particles was first discovered in finished product lot #1902801, Deviation [redacted], dated 05/20/08.

OBSERVATION 2

An NDA-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, you failed to keep the USFDA informed of a failure of a distributed drug product not meeting the specifications established for it in the application. Market complaint was received on 03/23/09 related to particles matter in Metformin Oral Solution, lot #1987071 and you confirmed such after receiving the complainant sample on 04/01/09. The test for clarity of the solution clearly requires that the sample should be clear, free from particles or foreign matter and no precipitate should be observed. It was not until 05/22/09, two month later, that your investigation concluded that the particles may be attributed to a worn nozzle seal on the filling machine. Nevertheless, your investigation was found inadequate and all suggested corrective actions have not been implemented as stated in the investigation.

In addition, your ANDA 78-053, Sertraline Hydrochloride Oral Concentrate, 20 mg/mL NDA-Field Alert report, dated 03/26/09 for lots (1728799, 1728800, and 1729098) was submitted late. Even though you claimed the product to be expiring

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Ave. Jamaica, NY 11433 (718) 340-7000 Fax:(718) 662-5661	07/13/2009 - 08/12/2009* FEI NUMBER 3001236657

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Robert Patton, Vice President & General Manager

FIRM NAME	STREET ADDRESS
Ohm Laboratories, Inc.	34 West Fulton Street
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Gloversville, NY 112078	Rx Drug Manufacturer

by the time of this filing, your stability study started on 01/31/07 and you complete the testing of the subject product on 03/02/09.

ANDA 76-529 LORATADINE SYRUP (ORAL SOLUTION, USP), 5 mg/5 mL and ANDA [redacted] (b)(4)

OBSERVATION 3

An adequate number of batches of each drug product are not tested nor are records of such data maintained to determine an appropriate expiration date.

Specifically:

a) There is no data in place nor maintained since inception of your company and prior to April 2008 for all products manufactured that were used for stability studies including exhibits batches in support for ANDA's as well as for your yearly stability lots. You have stability samples stored inside the stability chambers located in the warehouse where every employee may have access, as well as in the refrigerators located inside the laboratory which are (b)(4) located approximately [redacted] apart. These samples were noted to be in the same configuration/orientation (horizontal/vertical); it appears that you can not guarantee or ascertain 100% that samples stored in the refrigerators were ever used in exchange of the stability samples stored inside the stability chambers since there are no records.

b) The new formulation of ANDA 76-529, Loratadine Oral Solution, USP 10 mg/10 mL, submitted to the agency on September 25, 2007 as part of a CMC - Prior Approval Supplement. This PAS provides for a new preservative (b)(4) [redacted] to be added to the formulation as part of the company corrective action due to the recall of multiple lots of drug products that failed approved specification for Total Related Substances, Highest Individual Unknown Impurity, and the known impurity 2-hydroxy methyl loratadine limits.

(b)(4) Your stability protocols for Lot #2070701 (STB-003/007- Tropical Fruit Punch Flavor) & for Lot #2080701 (STB-006/07- Grape Flavor), do not asses the concentration of [redacted] There are no established parameters for in-process specification, finished product release specification as well as stability. In addition, you do not test for concentration of this preservative added to the formulation.

c) You submitted a CMC Prior Approval Supplement in October 19, 2007 for the new flavoring agent (Grape Flavor) to the USFDA including up to three month of stability data for lot #2080701, but you omitted to provide the (b)(4) complete stability summary report for three studies with the [redacted] container that may be considered crucial to determine an appropriate expiration date of the drug product. The following are stability data not provided in the PAS-CMC.

(b)(4) - [redacted] % RH Horizontal CRT

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Ave. Jamaica, NY 11433 (718) 340-7000 Fax:(718) 662-5661	07/13/2009 - 08/12/2009* FEI NUMBER 3001236657

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Robert Patton, Vice President & General Manager

FIRM NAME	STREET ADDRESS
Ohm Laboratories, Inc.	34 West Fulton Street
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Gloversville, NY 112078	Rx Drug Manufacturer

(b)(4) - [redacted] % RH Vertical Accelerated
- [redacted] % RH Vertical CRT

d) The number of units placed on stability according to both Loratadine's Stability Protocols, differ from the number of units sampled for stability and documented in the BMR's for Lot #2070701 and Lot #2080701. There are no records in place to demonstrate the location and storage condition of the remaining units.

(STB-006/07), dated 06/29/07 for Lot 2080701 – Grape Flavor				
16 oz - Sampled as per BMR for Stability	*Stored in Stability Chamber as per Protocol*	*2 oz – Sampled as per BMR for Stability*	*Stored in Stability Chamber as per Protocol*	*Container Closures*
[redacted] units	[redacted] units	[redacted] units	[redacted] units – Difference of [redacted] units	PETE
[redacted] units	[redacted] units	[redacted] units	[redacted] units – Difference of [redacted] units	GLASS
There is a difference of [redacted] units		There is no uniformity between the number of units sampled as per BMR for stability in each lot/protocols.		

(b)(4)

(STB-003/07), dated 05/25/07 for Lot 2070701 – Tropical Fruit Punch Flavor				
16 oz - Sampled as per BMR for Stability	*Stored in Stability Chamber as per Protocol*	*2 oz – Sampled as per BMR for Stability*	*Stored in Stability Chamber as per Protocol*	*Container Closures*
[redacted] units	[redacted] Units	[redacted] units	[redacted] Units - Difference of [redacted] units	PETE
[redacted] units	[redacted] Units	[redacted] units	[redacted] Units - Difference of [redacted] units	GLASS
There is a difference of [redacted] units on each type of container closures		There is no uniformity between the number of units sampled as per BMR for stability in each lot/protocols.		

(b)(4)

There is a statement in the firm's stability protocol for Loratadine in cold chamber of samples to be analyzed only on demand when required. It was observed that refrigerators within the laboratory contain samples of Loratadine, Ranitidine and other drug products as well system suitability standards solution with no expiration. No equipment usage log, no traceability, no inventory performed by the firm with respect to these refrigerators.

(b)(4) e) The number of units placed on stability according to the [redacted] Protocol, differs from the number of units sampled for stability that was documented in the BMR for exhibit batch [redacted]. There are no records in place to demonstrate the location and storage condition of the remaining units.

(b)(4)

(STB-[redacted]) dated 09/16/05 for Lot [redacted] Liters		
16 oz - Sampled as per BMR for Stability	*Stored in Stability Chamber as per Protocol*	*Container Closures*
[redacted] units	[redacted] units	PETE

(b)(4)

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Ave. Jamaica, NY 11433 (718) 340-7000 Fax:(718) 662-5661	07/13/2009 - 08/12/2009* FEI NUMBER 3001236657

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Robert Patton, Vice President & General Manager

FIRM NAME	STREET ADDRESS
Ohm Laboratories, Inc.	34 West Fulton Street
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Gloversville, NY 112078	Rx Drug Manufacturer

QUALITY SYSTEM

OBSERVATION 4

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:

(b)(4)

a) There is no written procedure for the specific use of the laboratory refrigerators set at [redacted]°C to [redacted]°C" where stability samples for Loratadine Oral Solution exhibit batches #2070701 and #2080701 as well as Ranitidine HCL exhibit batch #5750601 were observed, among others. These samples were observed to be stored and arranged in the same positions as those located in the stability chambers, horizontal and vertical and no inventory/refrigerator log is in place to show history/movement of the materials within.

(b)(4) b) The lab refrigerators: ID #[redacted] are used as cold storage ([redacted]°C) for stability samples, laboratory solutions, reference standards, and chromatographic solutions. There is no traceability, at all, for samples stored inside these refrigerators. Examples of drug products (exhibit batches) currently observed to be store inside these refrigerators are:

(b)(4)

Refrigerator [redacted]				
Product Name	**Lot No.**	**Stability Protocol No.**	**Qty.**	**Container/Presentation**
Loratadine Oral Solution	2080701	STB-006/07	[redacted]	16 oz. PETE
			[redacted]	2 oz. PETE
			[redacted]	16 oz. Glass
			[redacted]	2 oz. Glass
Ranitidine HCl	5750601	STB-003/06	[redacted]	4 oz. PETE
			[redacted]	16 oz. PETE
Refrigerator [redacted]				
Loratadine Oral Solution	2070701	STB-003/07	[redacted]	16 oz. PETE
			[redacted]	2 oz. PETE
			[redacted]	16 oz. Glass
			[redacted]	2 oz. Glass

(b)(4)

(b)(4) (b)(6) The stability protocols include some information of samples pulled from the refrigerators and tested as recorded in the stability summary reports. However, the protocol itself does not mention the intention of the ([redacted]°C) study and your employees [redacted] & [redacted] only stated that it was for R&D purposes. You did not provide any information to the agency in terms of samples stored at this condition.

The chambers are not continuously monitored for temperature. The daily temperature check corresponding to the 03/04/09 was not performed.

(b)(4)(c) (b)(6) A total of 4 unauthorized spiral pocket notebooks were found inside your Quality Control Laboratory "Chemistry section." The spiral pocket notebook [redacted] was found inside a drawer in your QC Laboratory center bench. Spiral pocket notebooks [redacted] was found in the drawers of Chemist [redacted] desk. Chemist [redacted] stated that they were mainly use to record daily activities that he has to do. Chemist [redacted] stated that he used such notebooks to review the chemicals in the laboratory. These spiral pocket notebooks appear to be issued and used for laboratory operation. There is no established written procedure for the handling of these notebooks in the laboratory and in any other area. Review of these spiral pocket notebooks were found to have written notes, such as and not limited to:

(b)(4)
- Book [redacted] chemicals, date of analysis, batch numbers, type of analysis, equations or data
- Book [redacted] from 4/27/09 to 4/30/09 and 5/1/09, 5/4/09, 5/5/09 and 5/6/09 daily activities to do in the laboratory
- Book [redacted] OT - chemicals, batch numbers status of samples date and samples status, telephone numbers, "I am not considering as Chemist," OT and "Local FDA," and batches
- Book [redacted] type of analysis, batch numbers, equation or data

(b)(4) e) There is no standard operating procedure in place that describes the steps to be followed during an Out-of-Trend (OOT) Investigation. The investigation for [redacted] batch [redacted], assay failing result, discovered by the FDA Team during review of your laboratory notebook was classified as an OOT investigation, it omitted the first OOS test result obtained; besides, the "OOT Investigation" performed was inadequate.

OBSERVATION 5

Written production and process control procedures are not documented at the time of performance.

Specifically:

a) Your stability program was found questionable. It was noted that the records of an employee documenting samples pull out dates, for different stability studies of your drug products, when in fact the employee was not physically onsite on the day of the event. Furthermore, the employees accepting the samples to be analyzed can not confirm the accuracy of the documented date. The following are examples:

(b)(6)

Product	Lot #	Protocol #	Interval	Date recorded	Day	Building Alarm	[redacted] e-Time record
Loratadine	2070604	STB-016/06	6 mo.	7/7/2007	Saturday	No record	Out
			9 mo.	10/7/2007	Sunday	No record	Out
	2080801-New API Supplier	STB-006/08	2 mo.	5/30/2009	Saturday	Open	Out
	2070701	STB-003/07	3 mo.	9/1/2007	Saturday	No record	Out

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Ave. Jamaica, NY 11433 (718) 340-7000 Fax:(718) 662-5661	07/13/2009 - 08/12/2009* FEI NUMBER 3001236657

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Robert Patton, Vice President & General Manager

FIRM NAME	STREET ADDRESS
Ohm Laboratories, Inc.	34 West Fulton Street
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Gloversville, NY 112078	Rx Drug Manufacturer

						(b)(4)	
	2080701	STB-006/07	1 mo.	7/29/2007	Sunday	Open	Out
			3 mo.	9/29/2007	Saturday	[redacted] alarm	Out
			6 mo.	12/29/2007	Saturday	Open	In
			9 mo.	3/29/2008	Saturday	No record	Out
	2070801 –New API Supplier	STB-005/08	2 mo.	5/30/2009	Saturday	Open	Out
Lorazepam	5190701	STB-008/07	1 mo.	9/22/2007	Saturday	No record	Out
			18 mo.	2/22/2009	Sunday	No record	Out
(b)(4) [redacted]	[redacted]	[redacted]	3 mo.	1/4/2009	Sunday	No record	Out
Metformin	1541054	STB-004/05	18 mo.	2/3/2007	Saturday	No record	In
(b)(4) [redacted]	[redacted]	[redacted]	12 mo.	9/22/2007	Saturday	No record	Out
			18 mo.	3/22/2008	Saturday	No record	Out
	[redacted]	[redacted]	3 mo.	12/27/2008	Saturday	Open	In - No activity within vault
Ranitidine	5750601	STB-003/06	24 mo.	3/22/2008	Saturday	No record	Out
Nortriptyline	1505270	STB-002/05	9 mo.	1/7/2006	Saturday	Open	Out
			24 mo.	4/7/2007	Saturday	No record	Out

No record = building alarm armed all weekend
Open = someone disarmed the building at some point on that date

(b)(4) b) The dispensing record of the [redacted] exhibit batch [redacted] shows [redacted] raw material lot [redacted] to be weighed by [redacted] on 08/31/05 and checked by [redacted] one day before, 08/30/05. (b)(6) (b)(4)

c) According to your records and walkthrough of the facility during the manufacturing of the second validation batch (2048020) of Oxcarbazepine Oral Suspension that was converted to a trial batch after the product was manufactured, it was noted that you failed to document concurrently with the specific operations taking place. In addition, your (b)(4) employees documented ahead in sections of the BMR's such as the room and vessel to be used. Step [redacted] related to the suspension preparation section, an unknown employee completed the information with the room number and tank # to be used, but the "performed by" and "check by" sections were left blank. The same occurred with the (b)(4) ongoing activities related to step [redacted] which it was observed to be completed/executed.

(b)(4) The Plant Manager stated that it was a miscommunication with the employees, but then stated it to be confusion with the step [redacted] which calls for the use of a different vessel.

d) According to the batch manufacturing record for the rejected Sertraline Hydrochloride Oral Solution intended (b)(4) exhibit batch [redacted], materials were weighed and its accuracy were verify in step [redacted] on 07/23/05. This (b)(4) batch was rejected due to power failure of mixer [redacted]. However, you failed to confirm the dispensing of the (b)(6) material to this batch after operator '[redacted]' embossed his initials in the "Wgd. By" column to document the dispensing of the active pharmaceutical ingredient and then strikeout his initial meaning; no action was ever performed.

e) The batch manufacturing records for the screened Sertraline APIs (lot #1546771, #1546772 & #1546773) previously intended to be used in exhibit batch (b)(4), rejected due to power failure of mixer (b)(4), indicates that the material were processed on 07/23/05. The BOM or first page of these batch manufacturing records shows that operator (b)(6) acknowledge the material been dispensed on 07/23/05, but then overwrite such to convert it to 07/25/05. No explanation was provided.

OBSERVATION 6

Investigations of a failure of a batch or any of its components to meet any of its specifications 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.

No thorough assessment was made into any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically;

a) Metformin Oral Solution market complaint written investigation (b)(4) lot #1987071 received on 03/23/09 and closed on 05/22/09, failed to address other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy. All products manufactured at your facility utilized the same filling machine and your market complaint investigation claimed to be a process related issue.

b) Process Deviations Reports, (b)(4) dated 05/20/08 and (b)(4) dated 07/07/08 for Ranitidine HCl Solution lot #1902801 and for lots #1901358, 1902801, 1901850, 1902802, 1902803, 1902804, respectively, refers to floating particles of fiber and cardboard to be found in bottles of drug product.

- Despite your (b)(4) investigation report that states that the lot of components used (#1833698) were rejected (b)(4) bottles) of a batch size of (b)(4) bottles, there is no documentation available showing the rejection of these remaining bottles.

- There is no documentation to assure that the substituted component lot (1893610) was inspected as mentioned in (b)(4)

- You failed to expand the investigation into others lots of Ranitidine HCl manufactured using the questionable component lot (1833698).

- (b)(4) Change Control No. (b)(4) dated 07/23/08 for the implementation of the bottle washer does not properly asses the effectiveness of the equipment.

- You stated that Ranitidine HCl lots 1902802, 1902803 and 1902804 were manufactured using the bottle washer, a different lot of component and were 100% inspected. However, your (b)(4) Process Deviation Report, dated 07/07/08 only states that these lots met AQL criteria and no reference to the 100% inspection. In addition, no assessment was performed to the filling line with the new bottle washer.

- Current established in-process frequency for the filling and packaging operation failed to detect the particles in the first finished product lot mentioned in this deviation (1901358), manufactured with this questionable component lot (1833698). At least two independently 100% inspections were performed on the finished product lots #1901358, in addition to the Quality Assurance AQL inspection having detection of particles.

(b)(4) c) Finished product Investigation Report for assay of [redacted] content of [redacted] (b)(4) batch [redacted] with original assay result obtained as [redacted]%. This result was discarded without performing an OOS investigation and not notifying upper management of the event. The result reported was the re-injection of the sample (b)(4) preparation ([redacted]%) performed afterward.

- During the original analysis (6/26/09) two different columns [redacted] were used to obtain the resolution of [redacted] (Spec. NMT [redacted] after [redacted] injections of the system suitability solution. The solution was not re-injected to confirm the separation obtained in the injection [redacted]

(b)(6) (b)(4)

- There is no evidence in notebook [redacted]' that the sample was prepared again on 6/26/09 to confirm the result of [redacted]%.

(b)(4)

- Control sample of lots [redacted] were retested again with obtained results of [redacted]%, respectively. There is no evidence in notebook [redacted] that [redacted]ml from control lot [redacted] was taken to prepare the sample.

(b)(4)

- To conclude the investigation, three sample preparations of the lot in question were prepared with the control sample or with the laboratory sample. Laboratory notebook [redacted]' did not specify the sample used during the investigation. The results obtained were [redacted]%. Therefore, it is questionable as to what samples were used for the investigation.

(b)(4) (b)(4) d) Autoclave (serial [redacted] model # [redacted] failed to meet the yearly calibration performed by an outside technician on 02/17/09. The autoclave failed the empty distribution study of sterilization cycle not meeting the [redacted]°C for [redacted] minutes as require. You failed to evaluate the use of all materials sterilized with this autoclave before and after the failure. An example is: the sterilization of in-house Trypticase Soy Agar (TSA), lot #0202, manufactured prior to the 02/17/09 incident. This TSA lot was used during the Microbial Limit Test of Cetirizine HCl Oral solution finished product Lot #2000138 on 02/20/09.

(b)(4) e) No written investigation was ever performed nor documents detailing the impact of the power failure of the mixer on [redacted] during the manufacture of Sertraline Hydrochloride Oral Solution exhibit batch # [redacted] rejected on 07/23/05. This is a common piece of equipment utilized for other drug products manufactured at your site.

(b)(4) f) [redacted] result for the Loratadine Oral Solution [redacted]%, (specification of [redacted]% to [redacted]%) was observed during the in-process bulk assay of Loratadine by HPLC test of batch #1608385, tested on 02/14/06. At a minimum, your laboratory personnel did not re-inject the original samples as part of the investigation nor did they re-analyze the sample in duplicate with two analysts to confirm or identify the reason of the OOS. The investigation was transferred to production and no manufacturing errors were documented. You decided then to re-test the sample in triplicate with two analysts. The retest results average were within specifications [redacted]%) and you considered the in-process bulk to meet

(b)(4)

specifications. Your laboratory investigation concluded that the vial-cap of the sample preparation solution was not properly closed, therefore causing the low assay results for Loratadine and [redacted] The original non passing result was selectivity discarded from the passing results.

g) [redacted] result for the Sertraline Hydrochloride Form II [redacted]% spec. NMT [redacted]%) was observed during the raw material testing of related compounds of batch #1723370 tested on 01/03/07. The laboratory preliminary investigation was based on the laboratory check list. The sample was re-analyzed in triplicate with two analysts after no assignable cause was identified. The retest average results were within specifications (not detected & [redacted]%) then your tests were considered to meet the requirements. After the re-analysis, the laboratory assigned as possible root cause an air bubble or contamination. However, there is no assurance of the correct test results. The chemist did not proceed with the individual testing to prove the presence of air bubble in the system or glassware contamination. The original non passing result was selectively discarded from the passing results.

h) [redacted] result for the Lorazepam Oral Concentrate [redacted]% spec. NMT [redacted]%) was observed during the stability testing at the 3-month time period at [redacted]°C for related compounds testing for exhibit batch #5190701 tested on 11/21/07. The laboratory investigation was performed by the original analyst [redacted]) and it was signed by microbiologist [redacted] acting as a QC supervisor. In the preliminary investigation the chemist stated that glassware contamination, column carryover or the system generating a peak as a root cause. The same chemist reanalyzed the sample in triplicate without QA or QC authorization, as he was the only Chemist available in the laboratory. The retest results were [redacted]%, which are within the specification. The chemist could not demonstrate that it was due to a glass contamination, column carry over or system generation peak. Exhibit batch was approved at the QA/QC level. The original non passing result was selectively discarded from the passing results.

The SOP #2802 Reporting, Investigation and Disposition of Out of Investigation (OOS) Laboratory Results" effective on Feb. 26, 2009 does not required the retest of the original samples solutions as part of the laboratory investigation. The procedure also allowed additional testing by two analysts in triplicate if no assignable cause is established for the OOS result in the laboratory and shop floor/production investigation as states in section 5.11.

OBSERVATION 7

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

Specifically:

a) Recognizing that an Out-of-Specification Test Result was obtained in [redacted] specification of [redacted] as per requirement of your Quality Control/Quality Assurance Standard Operating Procedure for OOS Investigation, SOP Number 2802, Reporting, Investigation and Disposition of Out of Specification (OOS) Laboratory Results, effective 02/05/09 and previous revisions, it appears that you avoided to perform an Investigation for the assay test result of [redacted]. In addition, you failed to perform a complete assessment for the failure of the microbiology laboratory autoclave qualification that took place in February 2009. These incidents were never informed to the respective head of departments (QA/QC) which are NOT stationed here at your Gloversville, NY facility.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Ave. Jamaica, NY 11433 (718) 340-7000 Fax:(718) 662-5661	07/13/2009 - 08/12/2009* FEI NUMBER 3001236657

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Robert Patton, Vice President & General Manager

FIRM NAME	STREET ADDRESS
Ohm Laboratories, Inc.	34 West Fulton Street
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Gloversville, NY 112078	Rx Drug Manufacturer

b) Procedures are not established which are designed to assure that the responsible officials of the firm, if they are not personally involved in or immediately aware of, are notified in writing of investigations conducted or any unexplained discrepancy.

(b)(4) The QC Director and QA Associate Director which are stationed in a different State, as well as your Plant Manager and QA Supervisor were not notified of the failure of the Microbiology Autoclave Validation as well as the [redacted] OOS test result that was treated as an out-of-trend results (OOT), among others. According to your statements, they were not informed of the events, therefore, no assessment was ever performed to determine the magnitude, impact and significance of such failures.

(b)(6) On 08/06/09, the Vice-President QA & QC [redacted] stated that the information of the delay stability samples with the difference (in days) from pull out to testing were not informed by the local employees to upper management.

c) Your written procedure #2851, effective on April 13, 2009, Recordkeeping in Analytical Laboratory Notebooks, does not address the tools required to be used for documentation purposes at your facility. Pencil was used to identify peaks on the chromatograms for the related substances test. Examples are:

(b)(4)
- [redacted] exhibit batch [redacted] 16 oz HDPE bottle
- Loratadine Solution F/P 4oz marketed batches #'s 1612443, 1608385, 1608386 and 1608387
- Lorazepam Oral Concentrate batch #s 5190701 at [redacted] (vertical, horizontal, and dropper) and batch #5190701 [redacted] (horizontal, vertical, and dropper).
- Loratadine Solution exhibit batches #'s 2080701, 2070701

d) Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to the holding of rejected components, drug product containers, and labeling before disposition.

(b)(4) You have not instituted a system to avoid the destruction of original data related to rejected materials located inside the rejected cage area. The original data is not kept to assure that data related to destruction activities is exact, complete, and secure from alteration, and even erasure or loss. Furthermore, there is no documentation of the firm's employees, with date and time performing such activities. In addition, it was observed that the Plant Manager wrote in spaces of the current available destruction sheet during the plant tour. However, no dating and signature was made, as well as he did not verify physically the identity and description of the data he was updating. Materials listed on the subject form are: [redacted] drums of Riomet Oral Solution lot 2005514, Oxcarbazepine Suspension 300 mg/5 mL, lot #2048017 and components such as bottles and labels among others.

OBSERVATION 8

The number of qualified personnel is inadequate to perform and supervise the processing of each drug product.

Specifically:

- There is no QC Supervisor physically at your firm. According to the firm's Organizational Chart, there is a Director of QC, however, it was noted that he is stationed in Ohm Laboratories, NJ. There is no assurance that entirety of data necessary for investigation requiring management review is completely evaluated and assessed to determine if appropriate investigation was conducted and that appropriate corrective and preventive actions are carried out.

(b)(6)

- Your laboratory chemist [redacted] stated that Stability Summary Reports are not updated accordingly/concurrently after completion of the test because he has no time to perform such activities.

- It was noted that the Plant Manager formally re-trained employees when he is part of the failure and nobody trained him, or re-trained him, on the topic discussed.

(b)(4)

- Laboratory technician in charge of pulling samples from the stability chambers including the vault used for [redacted] was noted backdating on different stability protocols and verbally confirmed by stating: "it is hard to get two (2) peoples to open the vault"; "will fill in the date if left blank, at next time point, based on what the pull date is scheduled for."

OBSERVATION 9

Employees are not given training in the particular operations they perform as part of their function and written procedures required by current good manufacturing practice regulations.

Specifically:

a) The Plant Manager was observed signing many production records such as Equipment Usage Log, Batch Manufacturing Records, Dispensing Sheets, Reservation Cards, Process Order as well as Bill of Materials (first page of the BMR) was involve in the rejected batch of [redacted] as well as in the exhibit batch [redacted] manufactured in 08/31/05. It was noted that the Plant Manager confirmed the step [redacted] in lot [redacted] batch manufacturing record. According to the dispensing sheets the material was dispensed after been used in the compounding operation [redacted] was dispensed on 08/31/05 @ 8:07 PM and the [redacted] process of step [redacted] of the subject batch started on 8:05 PM (2 minutes before).

(b)(4)

In addition, [redacted] batch [redacted] manufactured in 12/2008, the Plant Manager as well as the production operator failed to document the actual stirring speed in step [redacted] Furthermore, he was involved in the compounding operation of Ranitidine HCl Solution, lot # [redacted] manufactured in 01/29/08. This last mentioned batch was rejected because the operator as well as the Plant Manager failed to add the entire amount of the API required during step [redacted] even though they signed and acknowledge that this was properly executed. In addition, "Line Clearance" for materials to be used was granted by the Plant Manager.

Investigation records show the Plant Manager giving training to the operators in batch card execution, instead of him receiving adequate training in all areas required as well.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Ave. Jamaica, NY 11433 (718) 340-7000 Fax:(718) 662-5661	07/13/2009 - 08/12/2009* FEI NUMBER 3001236657

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Robert Patton, Vice President & General Manager

FIRM NAME	STREET ADDRESS
Ohm Laboratories, Inc.	34 West Fulton Street
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Gloversville, NY 112078	Rx Drug Manufacturer

(b)(4) (b)(7)

b) The analytical method [redacted] (assay, related substances & preservative content) of [redacted] release testing and [redacted] (assay, chiral purity & related substances) of [redacted] have not been transferred between the issued laboratory [redacted] and the two Chemists currently working in the QC Laboratory. The methods were transferred on 8/12/05 before the two Chemists were hired. There are no records which document training in these two procedures. Additionally, there no records that both analysts were trained in the other standard test procedures (STP) currently in used in the laboratory.

(b)(6)

c) There are no records which document analyst validation for one or more of the following areas of analysis: assay by HPLC, assay by titrimetry, water determination by [redacted] identification by IR spectrophotometer, melting point apparatus and total aerobic microbial count as stated in written procedure 2811 Analyst Validation, effective on February 19, 2009.

d) Chemists, Microbiologist and Laboratory Technician reviewing analytical data without background and expertise in the area. Examples are:

(b)(6) (b)(4)
- Microbiologist [redacted] reviewing chemistry analysis performed by Chemists [redacted] or [redacted] notebooks [redacted] May 2009 [redacted] June 2009 & Lorazepam Oral Concentrate [redacted] November 2007 to December 07, 2007

(b)(6) (b)(4)
- Chemist [redacted] reviewing microbiological testing performed by Microbiologist [redacted] notebook [redacted] December 2008

(b)(6) (b)(4)
- Laboratory Technician [redacted] reviewing microbiological testing performed by [redacted] notebook [redacted] July 2009. TO WORK WITH [redacted] BY NUMBERING SUCH.

OBSERVATION 10

Complaint records are deficient in that they do not include the findings of the investigation.

Specifically:

(b)(4) (b)(7)

a) With the following market complaints [redacted] you claimed to know the basis of these particles as being the natural origin of the ingredients in the formulation of the [redacted] However, there is no scientific rationale with documented evidence to rule out any others foreign matters. In addition, you claimed to have your process filtered to eliminate any traces, but there is no indication that the filtration process occurred without any inconvenience during the manufacture of the subject product because you failed to monitor and document such in the respective batch manufacturing record. This same lot was subject to another complaint claiming that the product was found to be "watery" and ineffective as well as subject to an out-of-specification test result that was omitted, therefore not adequately investigated.

b) Confirmed Market Complaint received on 03/23/09 related to particles matter in Metformin Oral Solution, lot #1987071. Your 05/22/09 investigation concluded that the particles may be attributed to a worn nozzle seal on the filling machine; however, there is no written evidence to substantiate such.

LABORATORY SYSTEM

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Ave. Jamaica, NY 11433 (718) 340-7000 Fax:(718) 662-5661	07/13/2009 - 08/12/2009* FEI NUMBER 3001236657

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Robert Patton, Vice President & General Manager

FIRM NAME	STREET ADDRESS
Ohm Laboratories, Inc.	34 West Fulton Street
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Gloversville, NY 112078	Rx Drug Manufacturer

OBSERVATION 11

The written stability program for drug products does not describe the storage conditions for samples retained for testing.

Specifically:

a) There is no data/documentation available to show where stability samples pulled from the stability chambers were stored prior to being tested. The following are examples of drug products not immediately tested with difference (in days) from pull out date to testing date:

Product name	Batch #	Pack	Test Point	Test	Difference(in days) from pull out to testing
Metformin	1326373	4 oz HDPE	18 Month CRT	Analytical	[redacted] days
Metformin	1327834	4 oz HDPE	18 Month CRT	Analytical	[redacted] days
Metformin	1328455	4 oz HDPE	18 Month CRT	Analytical	[redacted] days
Sertraline	1728799	2 oz Glass	6 Month CRT	Analytical	[redacted] days
Sertraline	1728800	2 oz Glass	6 Month CRT	Analytical	[redacted] days
Sertraline	1729098	2 oz Glass	6 Month CRT	Analytical	[redacted] days
Nortriptyline	1680581	16 oz Glass	6 Month CRT	Analytical	[redacted] days
[redacted]	[redacted]	16 oz PETE	18 Month CRT	Analytical	[redacted] days

(b)(4)

b) There is no written standard operating procedure in place to control, secure, and allow authorized personnel to access the stability chambers. It appears that currently established system allows access to every employee of the firm with probability to misplace and/or change the stability samples without formal/official chain of custody.

c) The initiation of each stability study is not verified by a second and independently employee. The stability samples are placed in a chamber with no review of the amounts charged into the chamber as well as the require position of the units as per stability protocol.

OBSERVATION 12

Sampling and testing plans for drug products are not described in written procedures which include the number of units per batch to be tested.

a) You failed to have a written procedure that describes the number of units required to be collected for stability purposes. A discrepancy was noted with samples collected as per your batch manufacturing records against the stability protocols used for the same lot tested. There are more units reported in the batch records than in the stability protocol and no

information are available as to the whereabouts of the units in excess. Examples are and not limited to: Loratadine Oral Solution (STB-006/07), dated 06/29/07 for Lot 2080701 – Grape Flavor and Loratadine Oral Solution (STB-003/07), dated 05/25/07 for Lot 2070701 – Tropical Fruit Punch Flavor.

b) Your stability protocols illustrate more samples were collected when compared to the batch reconciliation form of the respective drug products. The following are examples:

Product Name	Batch No.	Pack Size	STB No.	Total Sampled for Stability	Samples Placed on Stability Per Protocol	Stability Samples Tested Per Protocol
Ranitidine	5750601	4 oz.	STB-003/06	[redacted]	[redacted]	[redacted]
Metformin HCl	AA192	4 oz.	STB-001/02	[redacted]	[redacted]	[redacted]
Metformin HCl	AA193	4 oz.		[redacted]	[redacted]	[redacted]
Metformin HCl	AA194	4 oz.		[redacted]	[redacted]	[redacted]

(b)(4)

OBSERVATION 13

The suitability of all testing methods is not verified under actual conditions of use.

Specifically, your analytical method for Related Substances of Metformin HCl Solution that was initiated at your NY Gloversville site, but was completed in New Jersey and submitted to the agency.

a) The Validation Protocol MVP002/03 and/or test method did not specify the spike level of the known impurities needed to perform the impurity test and impurity mix standard.

b) The gradient system used in this HPLC system is neither documented in the notebook nor in the chromatograms.

(b)(4)

c) The System Suitability solution chromatogram show signs of a shoulder in the [redacted] The firm failed to investigative such to determine if it was a degradation of the solution or a co-eluting peak.

d) The laboratory notebook does not reference where the test took place.

e) The HPLC configuration tubing at the time of method validation may not be similar to actual ones used possibly affecting the resolution. In addition, the Chromatographic Parameters of Validation Protocol No: MPV001/003 states that the column oven temperature was ambient. This analytical method was never transferred to your Gloversville, NY site.

OBSERVATION 14

Procedures describing the calibration of instruments and apparatus are deficiently written or followed.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Ave. Jamaica, NY 11433 (718) 340-7000 Fax:(718) 662-5661	07/13/2009 - 08/12/2009* FEI NUMBER 3001236657

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Robert Patton, Vice President & General Manager

FIRM NAME	STREET ADDRESS
Ohm Laboratories, Inc.	34 West Fulton Street
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Gloversville, NY 112078	Rx Drug Manufacturer

Specifically:

a) The written calibration procedure #2841 "Operation, Calibration and Maintenance of the [redacted] HPLC System" for HPLC Systems [redacted]) was found deficient in that it does not include a carry over test for the injector, detector noise & drift check, and the lamp hours and energy.

The instruments were used for the testing of raw material, in-process bulk and released testing of all marketed and distributed drug products in addition to exhibits batches for Loratadine Oral Solution 2080701 & 2070701, Sertraline Hydrochloride Liquid Concentrate lot #8400502, Lorazepam Oral Concentrate batch 5190701, [redacted] Ranitidine Hydrochloride batch #5750601, and [redacted]

b) A calibration certificate was provided showing that the thermometers used within the laboratory refrigerators were calibrated at the established interval, but that the vendor neglected to re-label it. Furthermore, the two calibration points evaluated were 0 °C and 100 °C, thus there was no challenge to the actual range of operation which were mentioned to be [redacted]°C to [redacted]°C.

c) No deviation was initiated for the lack of calibration for the UV/VIS. There was a gap in calibration records for the UV/VIS between 09/2006 and 10/13/2006. During the interim period, [redacted], exhibit batch [redacted] was analyzed on 10/03/2006 using this instrument.

d) The calibration program for your stability chambers is deficient in that it does not include specific directions and schedules. You do not perform re-qualification of the stability chambers. The original qualification of all chambers only included mapping studies with empty chambers. The chambers were never challenged by filling the storage space and proceeding with mapping studies. These chambers were observed to be fully loaded.

e) Vault [redacted] used for the storage of stability samples for [redacted] This room was never qualified, including initiation of mapping study, by the firm. Also, this room is only monitored for temperature with only one probe. The firm does not have the capability to monitor humidity within the room. The vault is approximately [redacted] long by [redacted] wide by [redacted] high.

f) Your firm does not have established emergency procedures for stability chamber malfunction, such as unexpected temperature and/or humidity changes. Written Procedure #2854 "OPERATION, MAINTENANCE, AND CALIBRATION OF STABILITY CHAMBERS AND WALK-IN COLD CHAMBERS" does not address emergency procedures.

OBSERVATION 15

Laboratory records do not include the initials or signature of a second person showing that the original records have been reviewed for accuracy, completeness and compliance with established standards.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Ave. Jamaica, NY 11433 (718) 340-7000 Fax:(718) 662-5661	07/13/2009 - 08/12/2009* FEI NUMBER 3001236657

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Robert Patton, Vice President & General Manager

FIRM NAME	STREET ADDRESS
Ohm Laboratories, Inc.	34 West Fulton Street
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Gloversville, NY 112078	Rx Drug Manufacturer

(b)(4) Specifically, Notebook [redacted] for Loratadine Oral Solution 10 mg/10 ml (New Formulation) used for documentation during the testing of exhibit batches [redacted] The following notebook pages were not verified for its accuracy, completeness and compliance.

(b)(4)
- Page 26 – 31 batch # [redacted] testing
- Page 57 – 60, 64 – 75 batch # [redacted] testing
- Page 76 – 79, 93 – 98 batches [redacted] stability testing
- Page 111 batches [redacted] stability testing
- Page 112 batch [redacted] Stability testing
- Page 128 – 135 batches [redacted] stability testing
- Page 247-250 and the last two pages without numbers, pages left in blank

(b)(6) Additionally, the C of A and the stability summary report were generated without verifying the laboratory notebook; this contradicts chemist [redacted] statement.

OBSERVATION 16

You failed to always maintain a backup file of data entered in the computer or related system as well as failed to have a procedure in place for backup operation to assure that the data is exact, complete, and secure from alteration, erasure or loss through keeping hard copy or alternate systems.

Specifically,

(b)(4) a) There is no procedure to backup data from the Personal Computer (PC) connected to the HPLC [redacted] and the UV/VIS Spectrophotometer [redacted]

b) There is no backup data for the UV/VIS Spectrophotometer, instrument use for testing the clarity of all finished drug products such as and not limited to Loratadine Oral Solution, Sertraline Hydrochloride Liquid Concentrate, [redacted] Ranitidine Hydrochloride Syrup, Metformin HCl Liquid Solution.

(b)(4) c) You maintain back-up data for the HPLC Systems since 04/2002 until May 26, 2009. No back-up of the systems has been performed since then. The instruments were used for testing raw material, in-process bulk, stability samples and finished product release. Examples are:

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Ave. Jamaica, NY 11433 (718) 340-7000 Fax:(718) 662-5661	07/13/2009 - 08/12/2009* FEI NUMBER 3001236657

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Robert Patton, Vice President & General Manager

FIRM NAME	STREET ADDRESS
Ohm Laboratories, Inc.	34 West Fulton Street
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Gloversville, NY 112078	Rx Drug Manufacturer

[redacted] (b)(4)

Product	Batch	Date	Test & Notebook Reference (per Instrument Log)
Cetirizine HCl Syrup	2032839 (Finished Product)	5/28/09	Related Substance [redacted]
Metformin HCl Sol.	1970946 (Stability 6 M)	6/03/09	Related Substance [redacted]
Sertraline HCl Sol.	1892522 (Stability 6 M)	7/2/09	Related Substance [redacted]
Nortriptyline HCl Sol.	2030744 (Stability Initial)	7/10/09	Assay [redacted]
[redacted]			
Cetirizine HCl Syrup	2032839 (Finished Product)	5/28/09	Assay [redacted]
Metformin HCl Sol.	1970946 (Stability 6 M)	6/3/09	Assay [redacted]
Sertraline HCl Sol.	1892522 (Stability 6 M)	7/2/09	Assay [redacted]
[redacted]	[redacted]	7/24/09	Assay [redacted]

(b)(4) (b)(4) (b)(4) (b)(4) (b) (4)

d) Original data for Nortriptyline HCL Oral Solution exhibit batch [redacted] HPLC chromatographic data for the stability studies of Long Term Study 3-month test point [redacted] C) and Accelerate [redacted] C) at 3-month test point was not available for review when requested.

(b)(4)

OBSERVATION 17

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.

Specifically:

a) The dedicated PC attached to HPLC Systems [redacted] was not secure in that the access to the [redacted] software was not granted by a unique username and password to avoid any omissions or changes to data. For example on 07/20/09, it was observed that both Chemists used a common username and password during an [redacted] software demonstration.

(b) (4)

b) This password can allow access to all levels of the software, including administrative capabilities such as editing methods sites and projects.

c) Security measures have not been instituted to prevent the computer screen from remaining active and not protected from unauthorized access.

d) No written procedure for this computer system that outlines the responsibilities and privileges of the laboratory personnel who utilize the software.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Ave. Jamaica, NY 11433 (718) 340-7000 Fax:(718) 662-5661	07/13/2009 - 08/12/2009* FEI NUMBER 3001236657

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Robert Patton, Vice President & General Manager

FIRM NAME	STREET ADDRESS
Ohm Laboratories, Inc.	34 West Fulton Street
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Gloversville, NY 112078	Rx Drug Manufacturer

OBSERVATION 18

Complete records shall be maintained for any testing and standardization of laboratory reference standards, reagents, and standard solutions.

(b)(4)

During the laboratory walkthrough on 07/13/09, several solutions were observed inside the refrigerator, [redacted], with precipitation that apparently are use for system suitability testing with no indication of preparation date, lot number, and expiry dates. Examples are but not limited to:

(b)(4)

- "[redacted] Solution" no expiration date and with precipitation. This solution was used to test the system suitability (resolution) in exhibit batch #[redacted]
- "Ranitidine Oral Solution Assay System Suitability Solution prepared on 07/29/07". This solution was used to test the system suitability (resolution) in commercial batch # 2022676 Ranitidine Oral Solution 15 mg/ml.

PRODUCTION SYSTEM

OBSERVATION 19

The master production and control records are deficient in that they do not include complete manufacturing, control, instructions, special notations, and precautions.

Specifically:

(b)(4) a) Critical steps in the manufacturing process of [redacted] that may contribute to the solubility of materials are not documented in the batch manufacturing record. Due to the lack of thorough and detailed instructions, the established batch manufacturing record allows you to discharge all the material at once leading to solubility and homogeneity issues. This was found in all drug products manufacturing batch records. The first Validation batch of [redacted] was rejected due to the presence of a white powdery substance trapped in the lower tank drain even though the previous step in the process required the operator to check for clarity of the solution.

(b)(4) In addition, step [redacted] of the [redacted] rejected lot [redacted] due to solubility issues. The process calls for the stirring of the solution for about [redacted] minutes or until a clear solution is obtained. This step was acknowledged by operators to be completed assuring that the solution was clear.

(b)(4) b) No evidence that the filtration process of [redacted] is documented in the batch manufacturing records nor monitored to determine if appropriate pressure was applied to the system in order to maintain integrity of the filter. Complaint file shows repetitive claims of a lot of the drug product having foreign matter issues and

product being ineffective. This is the same lot where the firm neglected to report the out-of-specification test result for assay.

c) Batch manufacturing records do not include the in-process results for each batch of drug product produced to allow responsible persons to review results and approved for further process.

(b)(4) d) The second Validation Batch [redacted] of Oxcarbazepine Suspension 300 mg/5 mL manufactured in 07/16/09 that was later converted to a trial batch, even though multiples trials batches were executed between this batch and the first Validation batch that failed viscosity testing results.

This suspension product is manually transferred to the filling line; the Batch Manufacturing Records has no provision on how to transfer the drug product as well as what are the minimum requirements to be met prior to transferring the product to the filling line. The product sits in the compounding vessel for [redacted]

(b)(4) [redacted]

e) Critical step in the manufacturing process of Oxcarbazepine Suspension 300 mg/5 mL that may determine the acceptable viscosity of the drug product are not documented in the batch manufacturing record. The addition of materials is a totally manual operation that vary from operator to operator and you have not established a constant flow rate; for example (weight/minute) for adding this materials that may add variability to the product and to the process.

f) All batch manufacturing records for every drug product are deficient in that they do not describe how critical raw materials and any other excipients are to be added, and when it is added to the vessels during the compounding operation, leading to possible variability in the process from operation to operation with different employees manufacturing the drug product.

OBSERVATION 20

Control procedures are not established which 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.

(b)(4) Specifically, at least two (2) lots of drug products have been rejected and one (1) manipulated during the validation phase. First validation batch for [redacted] was rejected due to solubility problems. A second batch manufactured was noted to have multiples cross-outs on the approved validation batch specifications, all related to the suggested stirring speed and no change control issued. It is not clear if this manually changed parameter was prior or after the product been manufacture. In addition, you failed to document the actual stirring speed on ste[redacted] and no deviation was ever lifted. This is the same step of Exhibit batch [redacted] submitted to the agency in support of ANDA [redacted] that according to the batch record as well as dispensing sheets you documented the charge of [redacted] to the vessel prior to dispensing such.

(b)(4) First validation batch of Oxcarbazepine Suspension, lot [redacted] was rejected due to not meeting viscosity specification, although excipients utilized for the manufacture of the lot are all meeting pre-determined specification.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Ave. Jamaica, NY 11433 (718) 340-7000 Fax:(718) 662-5661	07/13/2009 - 08/12/2009* FEI NUMBER 3001236657

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Robert Patton, Vice President & General Manager

FIRM NAME	STREET ADDRESS
Ohm Laboratories, Inc.	34 West Fulton Street
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Gloversville, NY 112078	Rx Drug Manufacturer

OBSERVATION 21

Each container of component dispensed to manufacturing is not examined by a second person to assure that the weight or measure is correct as stated in the batch records.

Specifically:

(b)(4)

a) Metformin HCl Solution, lot [redacted] was rejected because an overage of [redacted] g of artificial cherry flavor was added to the batch. The employees certify the respective step of the batch manufacturing record as having the required quantity and properly weighed. Page 3 of 13 of the batch manufacturing record for the lot in question states that the step related to check weighing has been deleted, "as the dispensing and manufacturing process are simultaneous," therefore, you can not guarantee that component weighing, measuring, and subdividing operations are adequately supervised.

b) Components for drug product manufacturing are not weighed, measured, and subdivided as appropriate. Specifically, there were at least two documented incidents in that the lots manufactured were rejected because not having enough material at the time of using the respective ingredients. They were: Metformin HCl Solution lot [redacted] terminated on 02/26/09 and a most recent one been Nortriptyline HCL Oral Solution lot [redacted] terminated on 06/29/09.

(b)(4)

In addition, [redacted] dated 05/04/2006, was raised as a result of [redacted]% for Loratadine Oral Solution (specification [redacted]%) was observed during the in-process bulk assay of Loratadine by HPLC for batch #1636732 tested on 05/03/06. Although, the laboratory performed a poor investigation, the production investigation stated that as a corrective action that dispensing/production supervisor will be present for all weighing/dispensing operations to observe and ensure strict adherence to the Dispensing Raw Materials SOP. The amount of Loratadine USP API added to the batch was insufficient due to the fact that the operator never tarred the weighing container prior to dispensing.

PACKAGING & LABELING SYSTEM

OBSERVATION 22

Samples of representative units were not collected and visually examined for correct labeling at the completion of finishing operations.

Specifically, representative units, for the visual examination of the immediate drug container label, trays, etc., are not sampled from the shipping container for any drug product lots after completion of the operation. Examples are:

- Ranitidine Syrup, 15 mg/mL, lot 2022677, packaged in 05/2009
- [redacted]

(b)(4)

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Ave. Jamaica, NY 11433 (718) 340-7000 Fax: (718) 662-5661	07/13/2009 - 08/12/2009* FEI NUMBER 3001236657

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Robert Patton, Vice President & General Manager

FIRM NAME	STREET ADDRESS
Ohm Laboratories, Inc.	34 West Fulton Street
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Gloversville, NY 112078	Rx Drug Manufacturer

- Cetirizine HCl Oral Solution, 1 mg/mL, lot 2043082, packaged in 06/2009, and
- RIOMET® (metformin hydrochloride oral solution), lot 2028358, packaged in 05/2009

OBSERVATION 23

Failure to reject any lot of components and drug product containers that did not meet the appropriate written specifications for identity, strength, quality, and purity.

You failed to provide information related to the remaining rejected bottles of component lot #1833698 that was found to contain floating particles of fiber and cardboard during the manufacturing of Ranitidine HCL lot 1902801 and 1901358.

OBSERVATION 24

Written procedures are not followed for the sampling and testing of components.

Specifically, you failed to follow your own standard operating procedure for sampling, testing and release of raw materials, packaging materials, in-process materials and finished product, SOP 2801, effective 09/16/08. According to the SOP and based on the sample size you were require to sample and test [redacted] bottles, where in facts you only performed the testing of [redacted] units of empty bottles of lot (1833698) on 12/19/07 used for the production of Ranitidine HCl that were involve with floating particles and fiber.

(b)(4)

Furthermore, your employees [redacted] stated that the inspection request form sent to your contract laboratory upon receiving the C of A was destroyed. Therefore, you cannot provide documentation of the actual amounts of units sent to the laboratory for testing.

(b)(4)

*** DATES OF INSPECTION:**
07/13/2009(Mon), 07/14/2009(Tue), 07/15/2009(Wed), 07/16/2009(Thu), 07/17/2009(Fri), 07/20/2009(Mon), 07/21/2009(Tue), 07/22/2009(Wed), 07/23/2009(Thu), 07/24/2009(Fri), 07/29/2009(Wed), 08/04/2009(Tue), 08/05/2009(Wed), 08/06/2009(Thu), 08/07/2009(Fri), 08/12/2009(Wed)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Ave. Jamaica, NY 11433 (718) 340-7000 Fax:(718) 662-5661	07/13/2009 - 08/12/2009*
	FEI NUMBER: 3001236657

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Robert Patton, Vice President & General Manager

FIRM NAME	STREET ADDRESS
Ohm Laboratories, Inc.	34 West Fulton Street
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Gloversville, NY 112078	Rx Drug Manufacturer

FDA EMPLOYEES' NAMES, TITLES, AND SIGNATURES:

Kevin A. Gonzalez, Investigator

Chad N. Thompson, Investigator

Félix Maldonado, NRL Chemist

SEE REVERSE OF THIS PAGE	DATE ISSUED
	08/12/2009