DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 1500 Chicago, IL 60661-4716 (312) 353-5863 Fax:(312) 596-4187 Industry Information: www.fda.gov/oc/industry	01/22/2014 - 03/26/2014* FEI NUMBER 1420913

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Sivakumar Chinniah, Vice President Operations and Supply Chain

FIRM NAME	STREET ADDRESS
Morton Grove Pharmaceuticals, Inc.	6451 Main St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Morton Grove, IL 60053-2633	Human 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 I OBSERVED:

OBSERVATION 1

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

Your firm's Quality Unit is not fully monitoring Quality Systems designed to assure the safety and quality of drug products manufactured by your firm. This failure is evidenced by the continued uncontrolled use of "trial" injections during chromatographic testing to release drug products and monitor stability of drug products after this practice was cited in warning letters issued to two other Wockhardt facilities WL: 320-14-01 and WL: 320-13-21.

This is further evidenced by observations 2 - 12 below:

OBSERVATION 2

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that components, drug product containers, in-process materials, and drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically, the current SOP QC-102-077 Rev 15 "High Performance Liquid Chromatography Procedure" allows for "trial" injections. The procedure does not specify what type of injection should be made as a trial such as whether a standard or sample is to be used for the trial injection. This procedure states that these injections are for informational purposes only. However it does not specify what information the trial injections are to be used to obtain. The procedure allows for a copy of the data to be kept on the local drive. The procedure does not specify how the trial injections are reviewed by the quality unit. The procedure does not specify how a trial injection is to be processed and the firm does not collect, keep, or review audit trail information for trial injections. Examples of trial injections are listed in observation #3.

OBSERVATION 3

Laboratory records do not include a complete record of all data secured in the course of each test, including all graphs, charts, and spectra from laboratory instrumentation, properly identified to show the specific component, in-process material, lot tested, and drug product tested.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Brian D. Nicholson, Investigator Brian D Nicholson	03/26/2014

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 1500 Chicago, IL 60661-4716 (312) 353-5863 Fax:(312) 596-4187 Industry Information: www.fda.gov/oc/industry	01/22/2014 - 03/26/2014* FEI NUMBER 1420913

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Sivakumar Chinniah, Vice President Operations and Supply Chain

FIRM NAME	STREET ADDRESS
Morton Grove Pharmaceuticals, Inc.	6451 Main St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Morton Grove, IL 60053-2633	Human Drug Manufacturer

A. Trial injections do not include documentation of sample weights and preparation of sample solutions. In addition trial injection chromatogram data can not be traced to a documented sample solution prep. Examples of trial injections performed include:
   - Trial injection (b) (4) Trial 2013-07-23 16-53-13000001 - Trial Injection of a sample on 07/22/13. Samples run during this sequence include Megestrol Acetate Oral Suspension, USP 40 mg/mL lots UN1407 and UNS10300. The hardcopy for this trial injection was not retained in the analytical data packet per the firms' procedure.
   - Trial injection (b) (4) 2013-12-17 17-35-39 Trial 001 - Trial Injection of a sample on 12/17/2013. Samples run during this sequence include Oxybutynin Chloride Syrup, USP 5 mg/5mL lots UN1709 and UM1174.
   - Trial injection (b) (4) Trial Sample 13A 2013-11-07 14-14-58 - Trial Injection of a sample on 11/7/2013 - Samples run during this sequence include Fluticasone Propionate Nasal Spray, USP 50mcg per spray lots UN1630, UN1631.
   - Trial injection (b) (4) Trial Sample 1A 2013-12-03 15-49-07 - Trial Injection of a sample on 12/03/2013. Samples run during this sequence include Fluticasone Propionate Nasal Spray, USP 50mcg per spray lots UNS10538, UNS10615, UN1652, UN1734.
   - Trial Injection (b) (4) Trial 1 2013-10-30 11-27-30000001 - Trial Injection of a sample on 10/30/2013. Samples run during this sequence include Bromfed DM Cough Syrup lots UN1657, UN1658, and UN1124.

B. Chromatograms from trial injections are not always kept with the testing record. The trial injection named (b) (4) Trial 2013-07-23 16-53-13000001 was a trial injection of a sample on 07/22/13. Samples run during this sequence were Megestrol Acetate Oral Suspension, USP 40 mg/mL lots UN1407 and UNS10300. The hardcopy for this trial injection was not retained in the analytical data packet per the firms' procedure.

C. On 02/18/2014, I observed analytical data (b) (4) on the hard drives of the (b) (4) instrument (b) (4) with no assignable project folder. These files were not found on the server. The subject matter expert for these instruments, a Laboratory Manager, did not know why these files were on the hard drives. (b) (4) found on the local drive of the PC attached to instrument (b) (4) could not be identified as to what material, product, or run it represented.

OBSERVATION 4

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically, during my inspection of the QC laboratory on 02/18/2014, I found that (b) (4) raw data files and (b) (4) can be deleted from the hard-drive using the common PC login ID used by all Laboratory Analysts but may be used by any user. This deletion eliminates all record of performed sample analysis.

Some laboratory instruments are accessed through a general windows login accessible to all personnel and are not configured with administrative restrictions. This allows data stored on the hard drives of these instruments to be changed or deleted by any user. These laboratory instruments below use a general windows login which allows any user to log in and change or delete this data stored on the hard drives of these instruments. Note that despite the R&D or RD designation these instruments may be used by QC as evidenced by the shared systems use of R&D HPLC's (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Brian D. Nicholson, Investigator	03/26/2014

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 1500 Chicago, IL 60661-4716 (312) 353-5863 Fax:(312) 596-4187 Industry Information: www.fda.gov/oc/industry	01/22/2014 - 03/26/2014* FEI NUMBER 1420913

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Sivakumar Chinniah, Vice President Operations and Supply Chain

FIRM NAME	STREET ADDRESS
Morton Grove Pharmaceuticals, Inc.	6451 Main St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Morton Grove, IL 60053-2633	Human Drug Manufacturer

Instrument Name	Instrument ID
(b) (4)	(b) (4)

OBSERVATION 5

The written stability testing program is not followed.

Specifically, the Megestrol Acetate Oral Suspension USP first validation lot could not be found in the (b) (4) despite the fact that the (b) (4) logbook for long term stability studies ((b) (4)) indicated that the samples for the Megestrol Acetate Oral Suspension, USP first validation lot SP-06-2771-003 should be contained in this (b) (4) . The lot was also not recorded in the log for stability and retention sample destruction. The stability study manager did not know what happened to these samples.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Brian D. Nicholson, Investigator	03/26/2014

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 1500 Chicago, IL 60661-4716 (312) 353-5863 Fax:(312) 596-4187 Industry Information: www.fda.gov/oc/industry	01/22/2014 - 03/26/2014* FEI NUMBER 1420913

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Sivakumar Chinniah, Vice President Operations and Supply Chain

FIRM NAME	STREET ADDRESS
Morton Grove Pharmaceuticals, Inc.	6451 Main St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Morton Grove, IL 60053-2633	Human Drug Manufacturer

OBSERVATION 6

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,

The firm does not fully document OOS investigations. Initial phases of OOS investigations are performed under the firms procedure S-100-331 "Incident Procedure" rev 0. The procedure is deficient for use in performing initial phases of laboratory investigations in that it does not distinguish between phase 1 laboratory investigations and other incidents and does not describe acceptable investigational steps for phase I laboratory investigations. In addition the firm wholly documents assessment of a phase I laboratory investigation through the firms email system. An example of this type is Incident I-13-275. The stated problem was failure of bioassay testing of Nystatin raw material lots (b) (4) and (b) (4). The conclusion was analyst error due to overheating of the suspension/agar at some point during the assay and concludes that further investigation is not required. However the Media/Buffer Preparation record clearly shows appropriate media preparation and sterilization with no overheating. This Media Preparation Record was signed off as approved by the microbiologist and verified by the Microbiology Laboratory Manager.

OBSERVATION 7

The quality control unit lacks authority to review production records to assure that no errors have occurred and fully investigate errors that have occurred.

Specifically, quality data is not trended and tracked in a manner that would alert the firm of quality problems. The closed investigation into complaint C-13-0632 identified 194 of 258 complaints in a 12 month span were for 'spraying complications' related to nonfunctioning actuators for Fluticasone Propionate Nasal Spray. The investigation did not identify root cause. The subsequent corrective action (CAPA 12-QS-045 closed 04/11/13) consisted of trending complaints received according to the lot of the spray cap used for the finished product drug lot. The firm did not however identify acceptable alert and action limits for this metric nor did the firm define how a trend would be identified.

OBSERVATION 8

Changes to written procedures are not drafted, reviewed and approved by the appropriate organizational unit and reviewed and approved by the quality control unit.

Specifically, Procedures for change control do not include control of changes made to critical process parameters after validation of these parameters and prior to production implemetation in the form of a master batch record.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Brian D. Nicholson, Investigator	03/26/2014

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 1500 Chicago, IL 60661-4716 (312) 353-5863 Fax:(312) 596-4187 Industry Information: www.fda.gov/oc/industry	01/22/2014 - 03/26/2014* FEI NUMBER 1420913

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Sivakumar Chinniah, Vice President Operations and Supply Chain

FIRM NAME	STREET ADDRESS
Morton Grove Pharmaceuticals, Inc.	6451 Main St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Morton Grove, IL 60053-2633	Human Drug Manufacturer

OBSERVATION 9

Time limits are not established when appropriate for the completion of each production phase to assure the quality of the drug product.

Specifically, the firms definition of "Total Hold Time" per QO-101-126 rev 9 does not include time a product may be held in (b) (4) . An example is for the new product (b) (4) (b) (4) mL the validated parameter of (b) (4) hours hold time did not include the time the product is held (b) (4) . The master batch record therefore does not track or document time held (b) (4) to ensure that the validated hold time of (b) (4) hours is not exceeded.

OBSERVATION 10

Buildings used in the manufacture, processing, packing or holding of drug products are not maintained in a clean and sanitary condition.

Specifically, procedures for cleaning and sanitization do not include all areas and equipment. An example is the catch basin underneath the warm air hand dryer is not included in cleaning procedures or cleaning checklists. This catch basin is attached to the wall however is not attached to a drain. The catch basin has a cover with a screened end through which excess water shook off hands is to drain into the basin where the water is collected and remains stagnant. On 03/04/14, I observed that this catch basin contained stagnant water with white floating mold-like pieces. In addition the underneath of the catch basin cover had a black mold-like film covering the mesh area.

OBSERVATION 11

GMP training is not conducted to assure that employees remain familiar with CGMP requirements applicable to them.

Specifically, I reviewed training records for five employees and observed that two of these employees did not have documented training in CGMP's.

OBSERVATION 12

Production personnel were not practicing good sanitation and health habits.

Specifically, on 03/04/14 while in the gowning area prior to entering the drug manufacturing area I observed an employee enter the gowning area and proceed directly into the manufacturing area without washing and sanitzing his hands as is the firms procedure SOP S-100-311 "Personnel Practices in Production Area".

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Brian D. Nicholson, Investigator	03/26/2014

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 1500 Chicago, IL 60661-4716 (312) 353-5863 Fax:(312) 596-4187 Industry Information: www.fda.gov/oc/industry	01/22/2014 - 03/26/2014* FEI NUMBER 1420913

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Sivakumar Chinniah, Vice President Operations and Supply Chain

FIRM NAME	STREET ADDRESS
Morton Grove Pharmaceuticals, Inc.	6451 Main St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Morton Grove, IL 60053-2633	Human Drug Manufacturer

*** DATES OF INSPECTION:**
01/22/2014(Wed), 01/23/2014(Thu), 01/28/2014(Tue), 01/29/2014(Wed), 02/03/2014(Mon), 02/04/2014(Tue), 02/06/2014(Thu), 02/10/2014(Mon), 02/11/2014(Tue), 02/18/2014(Tue), 02/19/2014(Wed), 02/27/2014(Thu), 02/28/2014(Fri), 03/04/2014(Tue), 03/12/2014(Wed), 03/25/2014(Tue), 03/26/2014(Wed)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Brian D. Nicholson, Investigator	03/26/2014