DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612 (949) 608-2900 Fax:(949) 608-4417 Industry Information: www.fda.gov/oc/industry	12/15/2015 - 12/22/2015* FEI NUMBER 3008927138

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Stephen C. Morton, CEO

FIRM NAME	STREET ADDRESS
Morton Drug Company dba Morton LTC	201 E. Bell Street
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Neenah, WI 54956	Producer of Sterile Drugs

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:

OBSERVATION 1

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically,

A. The "clean room" where the ISO 5 (b) (4) resides and the ante room are not classified.
B. The pressure differentials between the "clean room"- ante room and the ante room - outside room were not monitored.
C. The (b) (4) the ISO 5 (b) (4) are not sterile.

OBSERVATION 2

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically, your firm did not establish an environmental monitoring procedure and failed to conduct environment monitoring of air, personnel, and surface during daily sterile product preparation within the ISO 5 (b) (4) even though the ISO 5 (b) (4) For example,

A. Active viable air monitoring is not performed in the ISO 5 (b) (4) during preparation of sterile drug products.
B. Environment monitoring of the ISO 5 (b) (4) (b) (4) is not conducted at the end of each day when sterile drug products are prepared.
C. Microbiological monitoring of the (b) (4) is not performed each day after sterile drug product is prepared.
D. The pressure differential results on ISO 5 (b) (4) were not documented during the preparation of sterile products.
E. When the ISO 5 (b) (4) . There is no documented evidence demonstrating that the aseptic condition can be (b) (4) to the unclassified environment.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Liming Zhang, Investigator Ariel Cruz Figueroa, Investigator	12/22/2015

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612 (949) 608-2900 Fax:(949) 608-4417 Industry Information: www.fda.gov/oc/industry	12/15/2015 - 12/22/2015* FEI NUMBER 3008927138

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Stephen C. Morton, CEO

FIRM NAME	STREET ADDRESS
Morton Drug Company dba Morton LTC	201 E. Bell Street
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Neenah, WI 54956	Producer of Sterile Drugs

OBSERVATION 3

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

Specifically, your firm's practice of visual inspection is deficient in that you do not have procedure requiring 100% visual inspection of the finished drug products and documenting the results of such visual inspection. For example,

A. On 12/15/2015, your pharmacy technician, (b) (6), prepared a batch solution of Cefazolin (batch number 121515ad). A total of (b) (4) bags of the finished product containing 2 g of Cefazolin in 100 mL of 0.9% Sodium Chloride sterile solution were prepared. Upon completion of the preparation, your pharmacist, (b) (6) performed verification of the preparation documents and labels. However, neither the pharmacy technician nor the reviewing pharmacist performed visual inspection of the products.
B. On 12/18/2015, your pharmacy technician, (b) (6) prepared (b) bags of Cubicin product each containing 363 mg of Cubicin in 50 mL of 0.9% Sodium Chloride sterile solution. Upon completion of the preparation, your pharmacist, (b) (4), (6) performed verification of the preparation documents and labels. However, neither the pharmacy technician nor the reviewing pharmacist performed visual inspection of the products even though this deficiency has been brought up to the firm's management attention on 12/15/2015.

OBSERVATION 4

Results of stability testing are not used in determining appropriate storage conditions and expiration dates.

Specifically, your firm has prepared Clindamycin sterile drug product with 900 mg Clindamycin in 100 mL 0.9% Sodium Chloride solution on (b) (4). Each day's preparation generated (b) bags of products. These products were assigned the beyond use date (BUD) of 9 days at room temperature. There is no stability study demonstrating that this product is stable for 9 days under room temperature. Your firm acknowledged that this BUD was incorrect and should have been assigned not more than 30 hours at room temperature. All (b) (4) bags of this product have been distributed to one patient and have already been administered.

OBSERVATION 5

Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically, the gowning practice is not sufficient for the sterile drug production operation. Employee requires only a pair of non-sterile glove for the preparation of sterile products. For example,

A. On 12/15/2015 prior to preparing batch solution Cefazolin product (batch number 121515ad), your firm's pharmacy technician, (b) (4) (b) (4), (b) (6) unprotected

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Liming Zhang, Investigator LZ Ariel Cruz Figueroa, Investigator	12/22/2015

arms, face, neck, hair, and street clothing were all exposed (b) (4).

B. On 12/18/2015 prior to preparing Cubicin product, your firm's pharmacy technician, (b) (6), (b) (4) Even though (b) (6) wore a mask during the cleaning process, (b) (6) unprotected arms, part of (b) (6) face, neck, hair, and (b) (6) sweater were all exposed (b) (4)

OBSERVATION 6

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.

Specifically, the media fill studies that were used to validate the aseptic techniques and to qualify individual employee for the sterile product preparation were deficient in that,

A. There was no environment monitoring done (b) (4) the ISO 5 (b) (4) during media fill study.
B. The record of media fill re-qualification study conducted on (b) (4) for pharmacy technician, (b) (6) showed that the sample incubation temperature reached 38°C which exceeded the acceptable range of (b) (4)°C. No investigation was conducted and documented. This media fill study result was accepted as is and the technician was allowed to continue preparing sterile products. To the date of this inspection, this employee has compounded (b) (4) sterile products since (b) (6) recent re-qualification media fill study on (b) (4)
C. None of the media fill study records documented the identification of the critical equipment (incubator) and its calibration status.

OBSERVATION 7

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically, the cleaning agent (b) (4)) and (b) (4) disinfectants ((b) (4)) that are used to clean and sanitize the ISO 5 (b) (4) area are not sterile.

* DATES OF INSPECTION:
12/15/2015(Tue), 12/16/2015(Wed), 12/17/2015(Thu), 12/18/2015(Fri), 12/22/2015(Tue)