

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

DISTRICT ADDRESS AND PHONE NUMBER

4040 North Central Expressway, Suite 300
Dallas, TX 75204
(214)253-5200 Fax: (214)253-5314

DATE(S) OF INSPECTION

8/10/2015-8/21/2015*

FBI NUMBER

3006031801

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Eddie W. Glover, CEO / Co-Owner

FIRM NAME

US Compounding Inc.

STREET ADDRESS

1270 Don's Lane

CITY, STATE, ZIP CODE, COUNTRY

Conway, AR 72032

TYPE ESTABLISHMENT INSPECTED

Outsourcing Facility

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 the system for cleaning and disinfecting the equipment to produce aseptic conditions.

Specifically,

- A. Your firm's failed to use sporicidal disinfectants in response to any environmental monitoring findings of spore-forming organisms. When the past 6 months of cleaning logs were reviewed, no documentation of use of a sporicidal agent could be demonstrated prior to March of 2015.

5 of 11 initial sterility failures from 2014 to present have occurred due to the presence of spore forming organisms. A comprehensive investigation was not performed. These initial sterility failures are summarized below:

- Testosterone 37.5mg Pellet produced on 11/06/2014 (Lot Number: 20140611@8) tested positive for Bacillus infantis
- Methylpred / Lido 40mg/1%/ml produced on ^{06/13/2014} 06/13/2014 (Lot Number: 20141305@3) tested positive for Bacillus thuringiensis
- Guaifenesin 5% produced on 04/25/2014 (Lot Number: 04252014@14) tested positive for Bacillus simplex
- Ketoprofen 10% produced on 03/24/2014 (Lot Number: 03242014@3) tested positive for Bacillus circulans
- Stanozolol 50mg/ml produced on ^{02/14/2014} 02/14/2014 (Lot Number: 02112014@41) tested positive for Bacillus cereus

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Lloyd D Payne, Investigator

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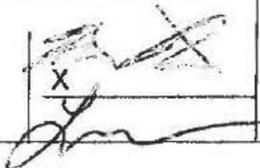
- B. Your firm had visible white powder residue on the ISO 5 Cleanroom Hood ^{(b) (4)} and on the adjacent ISO 7 Cleanroom floor during the production of Rocuronium (Lot Number: 20151108@35). When the issue was addressed with your firm, it was suggested that the white residue may be Methylprednisolone from the previous operation. Your firm failed to clean and disinfect surfaces that are visibly soiled. This surface remained visibly soiled during the manufacture of drug product.
- C. You move quantities of various production supplies used for aseptic manipulation into the ISO 7 Cleanroom where the ISO 5 (b) (4) is located without sanitizing the outside packaging before they are placed into the ISO 7 Cleanroom potentially increasing the risk of contamination of the control environment.

OBSERVATION 2

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

Specifically,

- A. Between 10/1/14 and 8/10/15, contact and viable air monitoring exceeded action limits without documentation of a complete investigation, implementation, and reassessment in response to excursions above action limits for environmental monitoring of contact surfaces and viable air in the aseptic processing areas. Monitoring included 33 instances actionable contamination ranging up to 49 CFU contact plate inside the ISO 5 (b) (4), 271 CFU contact plate in the (b) (4) housed in the ISO 8 Glass Storage and Prep and 63 CFU for viable air.
- B. Between 10/1/14 and 8/10/15, personnel monitoring exceeded action limits during the aseptic processing of sterile products to include 22 instances ranging up to 64 CFU for Gloves and 52 CFU for Personnel Clothing and Garb. You failed to investigate and take appropriate actions after counts for microbial contamination exceeded action limits.

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- C. Your firm failed to establish alert/action limits for microbial contamination counts on Gloves in ISO 7 areas and alert/action limits on Personnel Clothing & Garb associated with ISO 5 (b) (4) where aseptic processing of sterile products is performed.

OBSERVATION 3

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

Specifically,

- A. You failed to consistently review and investigate alerts when the pressure differentials dropped below the minimum set points of (b) (4) W.C. You reported the alarms for the minimum air pressure differential set points were eliminated during a correction made in June 2015, rendering the alarms non-functional.

The current Controlled Environment Performance Test and Certification Report performed on 8/3-4/2015 found that three of the (b) (4) air pressure differential gauges were not functioning properly or were in need of calibration including the gauges between the ISO 7 Cleanrooms (b) (4); (b) (4) and ISO 7 Anteroom (b) (4) and the ISO 8 Chemical Storage and the Unclassified Hall.

- B. During aseptic processing of Rocuronium (Lot Number: 20151108@35), it was observed that your firm opened and closed the door between the ISO 7 Anteroom (b) (4) and ISO 7 Cleanroom (b) (4) eight times in one minute. Later, we requested pressure readings between the anteroom and cleanroom for that corresponding time. From 2:53 - 2:55 PM the pressure differential, as measured by your firm changed from positive to negative pressure ((b) (4) to -0.0176). The set point for the positive pressure differential was (b) (4) W.C. Your firm failed to acknowledge and investigate the lack of positive pressures.

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C. The Controlled Environment Performance Test and Certification Report #90348AE6 dated (b) (4) (b) (4) and #90348AF4 dated (b) (4) did not include the dynamic conditions as employed by your firm which includes up to (b) (4) people in each of the ISO 7 cleanrooms at any given time and the use of (b) (4) in the ISO 7 room.

D. You failed to make required corrections to the Facility Engineering Controls as noted in the Air Safe report (Controlled Environment Performance Test and Certification Report) dated (b) (4) (b) (4) in a timely manner and continued to aseptically produce sterile products. The final recommendations for corrections in the report included making the appropriate adjustments to the HVAC system, which may include (b) (4) or (b) (4) to achieve the desired pressure differentials throughout the controlled areas and the calibration or replacement of air pressure gauges that monitor the room pressure between Cleanroom (b) (4) and Ante Room (b) (4). You reported the air pressure monitor between Cleanroom (b) (4) and Ante Room (b) (4) was replaced in February 2015 but could provide no evidence of such replacement. You attempted to make corrections to the air flow and air volume in May 2015 and the again in June 2015. The controlled environment performance test and certifications were not performed after each correction to the HVAC system and air pressure monitoring. Your firm continued to produce under these environmental conditions.

In addition, Controlled Environment Performance Test and Certification Report dated (b) (4) included the same deficiencies to the Facility Engineering Controls including making the appropriate adjustments to the HVAC system which may include (b) (4) or (b) (4) (b) (4) to achieve the desired pressure differentials throughout the controlled areas and the calibration or replacement of air pressure gauges that monitor the room pressure between Cleanrooms (b) (4) and (b) (4) and the Ante Room (b) (4) Storage Room (b) (4) and Ante Room (b) (4), Storage Room (b) (4) and Storage Room (b) (4) and Chemical Storage and the unclassified hall. As a result you failed to consistently provide a controlled environment during the production of all aseptically filled human and veterinary products between the (b) (4) controlled environment performance tests and certifications.

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Furthermore, your firm produced product from (b) (4) to (b) (4) on 08/11/2015. During this time, your firm measured pressure differentials between Anteroom (b) (4) and Cleanroom (b) (4). During this time, a number of negative pressure differentials were measured and are listed below:

DATE TIME STAMP	ALARM ACTIVE	ALARM LOW LIMIT	PRESSURE ON LCD	ROOM TYPE
(b) (4)	false	(b) (4)	-0.017594557	Positive
	false	(b) (4)	-0.017594557	Positive
	false	(b) (4)	-0.017594557	Positive
	false	(b) (4)	-0.006621005	Positive
	false	(b) (4)	-0.006713362	Positive
	false	(b) (4)	-0.006713362	Positive
	false	(b) (4)	-0.002258667	Positive
	false	(b) (4)	-0.006621005	Positive
	false	(b) (4)	-0.006621005	Positive
	false	(b) (4)	-0.006621005	Positive
	false	(b) (4)	-0.017594557	Positive
	false	(b) (4)	-0.017594557	Positive
	false	(b) (4)	-0.017594557	Positive
	false	(b) (4)	-0.005605309	Positive
	false	(b) (4)	-0.012487253	Positive
	false	(b) (4)	-0.012487253	Positive
	false	(b) (4)	-0.012903121	Positive
	false	(b) (4)	-0.017109128	Positive
false	(b) (4)	-0.017109128	Positive	
false	(b) (4)	-0.016184563	Positive	
false	(b) (4)	-0.016184563	Positive	
false	(b) (4)	-0.009553697	Positive	

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(b) (4)	false	(b) (4)	-0.009553697	Positive
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OBSERVATION 4

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established.

Specifically,

- A. Your firm does not perform media fills that simulate production or most challenging conditions. During production, a (b) (4) is (b) (4). During this process, the vials to be lyophilized, (b) (4) (b) (4) (b) (4). No media fills simulating this process is being conducted. Additionally, your media fills are not conducted to simulate the door opening and closing (b) (4) times in a single minute as observed between 2:30 and 2:55 PM on 08/11/2015. Instead, your media fills are conducted (b) (4).

Furthermore, your firm did not begin to implement the use of media fills until 09/24/2014. Additionally, your firm does not qualify operators' via media fills prior to conducting aseptic processes. As of 09/08/2014 the firm hired a new operator (b) (6). This operator was qualified for aseptic filling on 03/24/2015 and filled FENTANYL PF 50 ML (Lot Number: 20152403@28) on that same day. However, until 04/13/2015 (b) (6) was not qualified by a media fill.

- B. Your firm utilizes a (b) (4) to produce: HCG/B12 FDP 5,000U/600mcg/1ml, HCG/B12 FDP 10,000U/1,200mcg/2ml, Dapiprazole 0.5% Ophthalmic, Sincalide 3mcg, Sincalide 5mcg, Deslorelin 1.5mg/ml for SDV, Deslorelin & HCG 1.5mg/2000U/ml for SDV, Deslorelin 3mg/ml for MDV, and Deslorelin & HCG 3mg/4000U/ml for MDV. We observed the following for your firm's (b) (4) (b) (4):

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- 1) There is no qualification of all (b) (4) (b) (4) or validation of the lyophilization process.
- 2) The process was viewed in person as a staged process on 08/11/15. Additionally, video of the process occurring for production of HCG/B12 FDP - 10ML CONCENTRATE 10,000U (Lot Number: 20151008@5) during 08/10/2015 was reviewed. The following process was observed whereby the (b) (4)
a. The firm (b) (4) (b) (4), which stands an approximately (b) (4) feet tall and (b) (4) feet wide from the ISO 7 Storage Room.
b. The (b) (4) (b) (4) and "cleaned" with (b) (4) wipes. This "cleaning" process not been validated to sterilize the (b) (4).
c. The unit (b) (4) (b) (4) by a (b) (4).
d. Once in the (b) (4) adjacent to the ISO 5 hood.
e. The lyophilization (b) (4) is opened. The (b) (4) into the (b) (4) by (b) (4).
f. The unit is (b) (4).
g. The (b) (4) where the vials are (b) (4) (b) (4).
h. The (b) (4) is then (b) (4) (b) (4).
3) Per your Quality Control Director, room certification and smoke studies for the ISO 7 Cleanroom were not performed during the operation of the (b) (4).

OBSERVATION 5

Written procedures for sampling and testing plans are not followed for each drug product.

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Specifically, you failed to conduct a 100% visual inspection of Papaverine 3.6mg/mL + Phentolamine 0.4mg/mL + Atropine 0.04mg/mL lot 20152403@12 prior to its initial distribution of (b)(4) vials on 4/16/15 as office stock. SOP S19 entitled, Finished Product Testing Requirements, states in Section 9.1, "Immediately after compounding, and as a condition of release, each CSP unit, where possible should be inspected (b)(4) for evidence of visible particulates or other foreign matter." During the inspection, you retrospectively inspected the remaining inventory of lot 20152403@12 and found (b)(4) units passed and 18 units failed visual inspection.

Furthermore, during the visual inspection of the subsequent lot of Papaverine 3.6mg/mL + Phentolamine 0.4mg/mL + Atropine 0.04mg/mL lot (b)(4)(b)(4) was found on 8/18/15 to have failed visual inspection with a failure rate of 57.5% with (b)(4) units passing and 73 units failing visual inspection due to visible fiber like particles.

OBSERVATION 6

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.

Specifically, review of 2015 complaints revealed that 55 of 108 of the firm's complaints relate to broken testosterone, estradiol, and progesterone pellets. When discussed with you firm they stated that a number of formulation changes have been made to the testosterone pellets in order to address the complaints. However, your firm released batches of pellets without assessing the manner these formulation alterations affected product efficacy. In addition, no dissolution studies were conducted. An example of these alterations for Testosterone 200 MG Pellets is listed below:

- 1) Lot 20132210@12 is formulated with Povidone, Stearic Acid and Testosterone.
- 2) Lot 20141002@37 is formulated with Stearic Acid and Testosterone.
- 3) Lot 20141508@35 is formulated with Stearic Acid, Testosterone and Magnesium Stearate.

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- 4) Lot 20152601@10 is formulated with Stearic Acid, Testosterone and Magnesium Stearate. This lot is formulated (b) (4)(b) (4) and a (b) (4)(b) (4) relative to Lot 20141508@35.
- 5) In February 2015 your firm (b) (4)

OBSERVATION 7

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically, we observed the preparation of Morphine 2mg/2ml (1mg/ml) PF (preservative free) (Lot Number: 20151008@2) on 08/10/2015. This product is assigned a 180 day BUD without supporting stability data. Additionally, according to your firm's production logs, other examples of products assigned a BUD of 180 day without supporting stability data include Betamethasone PF 6MG/ML (Lot Number: 20152602@19) and Cupric sulfate pentahydrate PF (Lot Number: 20150402@5) 1.57 M.

Your firm's VP of Operations indicated that approximately (b) (4) sterile products are produced by your firm. The firm indicated that of all the products produced, only two (methylprednisolone acetate 80 mg/ml + Lidocaine 1% and Medroxyprogesterone acetate 150 mg/ml + Lidocaine 1%) are supported by stability indicating studies. Additionally, of the approximately (b) (4) sterile products, only 17 have end-point sterility (performed for (b) (4)).

OBSERVATION 8

Equipment used in the manufacture, processing, packing or holding of drug products is not of adequate size and suitably located to facilitate operations for its .

Specifically,

Your firm employs a (b) (4) water system for a (b) (4) used for cleaning of instruments, beakers, and final containers/closures used in aseptic processes. Your (b) (4) water system is inadequate due to the following:

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- A. Your firm lacks qualification or validation for the water system, despite your firm utilizing the system in the production process since August 2012.
- B. Testing for water quality was not conducted prior to the previous (b) (4) . Per testing by (b) (4) , the water failed conductivity tests. This apparent failure was not identified by your firm until FDA investigators addressed the issue with the firm.
- C. There are no filters on pressure relief valve for the holding tanks to prevent intake of contaminants.

OBSERVATION 9
Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications prior to release.

Specifically, on 08/14/2015, your VP of Operations indicated that they produce approximately (b) (4) sterile drug products containing preservative; however no preservative indicating studies have been performed. Your firm failed to test the preservative content in batches at time of release.

OBSERVATION 10
The labels of your outsourcing facility's drug products are deficient.

Specifically, the following information is not found on some of your drug product labels:

- The statements "This is a compounded drug" and "Not for resale."
- The containers of some of your drug products do not contain information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088.

Examples of drug product labels and containers that do not contain the above information:

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- A. Pain Cream #600 – Tablet-Based Formula, Meloxicam 0.09%, Topiramate 2.5%, Gabapentin 6% in Lidocaine/Prilocaine 2.5%/2.5%
- B. Testosterone 20% Gel, 30 GM
- C. Diethylstilbestrol 0.5 mg Capsule
- D. Enrofloxacin/Ketoconazole/Triamcinolone Otic in Lanolin 0.5/1/0.1% Ointment

OBSERVATION 11

Your outsourcing facility has not submitted a report to FDA identifying product produced during the previous six months as required by section 503B(b)(2)(A).

Specifically, the following products were produced and not identified on your report for the reporting period 12/1/14 – 5/31/15, which was submitted on June 19, 2015:

- A. Pain Cream #600 – Tablet-Based Formula, Meloxicam 0.09%, Topiramate 2.5%, Gabapentin 6% in Lidocaine/Prilocaine 2.5%/2.5% : Lot Number 20151008@10, Expiry Feb. 6th, 2016, Shipped 08/20/2015
- B. Testosterone 20% Gel, 30 GM : Lot Number 20151607@31, Expiry Jan. 2nd, 2016, Shipped 08/20/2015
- C. Diethylstilbestrol 0.5 mg Capsule : Lot Number 08052015@66, Expiry Feb. 1st, 2016, Shipped 08/19/2015

***DATES OF INSPECTION**

8/10/2015(Mon),8/11/2015(Tue),8/12/2015(Wed),8/13/2015(Thu),8/14/2015(Fri),8/17/2015(Mon),8/18/2015(Tue),8/19/2015(Wed),8/20/2015(Thu),8/21/2015(Fri)

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