

**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 6/12/2017-6/29/2017*
	FEI NUMBER 3004483441

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
Mr. James L. McCarley , CEO

FIRM NAME Cantrell Drug Company	STREET ADDRESS 7321 Cantrell Rd
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CITY, STATE, ZIP CODE, COUNTRY Little Rock, AR 72207-4144	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility
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This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

**DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:**

**OBSERVATION 1**

The quality control unit lacks authority to fully investigate errors that have occurred.

Environmental and Personnel Monitoring plates are not accurately enumerated to reflect colonies present.

(a) In an area housing numerous agar plates attributed by your firm as “trash” due to a lack of colonies, we observed several (b) (4) bags with agar plates containing growth. We (FDA Investigators and Microbiologist) discovered colonies on the following plates with intact plate covers (the readings were conducted by us on 06/12/2017 the same date your firm read the plates);

Plate Designation	Type of Monitoring	Counted (FDA)	Recorded (Firm)
(b) (4) of operator (b) (6) dated “6/5”	Personnel	1	0
(b) (4) of operator (b) (6) dated “6/5”	Personnel	1	0
(b) (4) of (b) (4) Hood (b) (4) dated “6/6”	Environmental	1*	0
(b) (4) of (b) (4) Hood (b) (4) dated “6/5”	Environmental	1*	0

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(b) (4) of (b) (4) dated "6/5"	Environmental	1	0
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\*Designates results that fail to meet specification of (b) (4) CFU in ISO 5 areas designated in P&P No. 7.230 titled "Environmental Monitoring Program for Area (b) (4)". The misreading of plates rendered this failing result unidentified.

Your Microbiologist stated that these plates were read by your firm's technician on 6/12/2017, prior to our arrival. Your Microbiologist also indicated that these plates designated as "trash" would not be further evaluated.

(b) The following plates with colonies were documented as containing no growth by your firm. We (FDA Investigators and Microbiologist) discovered discrepancies in colonies we observed versus those your firm recorded as follows:

Plate Designation	Type of Monitoring	Counted (FDA)	Recorded (Firm)
"6/6" from (b) (4) testing (b) (4)	Environmental	3	0
"6/6" from (b) (4) testing (b) (4) (b) (4)	Environmental	8	0
"6/6" from (b) (4) testing (b) (4) (b) (4)	Environmental	26	0
"6/6" from (b) (4) testing (b) (4) (b) (4)	Environmental	23	0

**OBSERVATION 2**

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

1. Upon our review of documents contained in your firm's (b) (4) shredding bins, we discovered that your firm discarded original documentation, including incidences, deviations and manufacturing occurrences not elsewhere officially documented. We identified the following records in bins intended for shredding (i.e. "trash"):

- a) An "Environmental – Internal Finding Report" (IFR) for lot 10204 (Sodium Bicarbonate 8.4%) without a quality assigned "Access #" (event number) was observed. The official deviations and internal findings reports were silent to this happening. Related to Observation 6, we identified that this exact lot was subject to an environmental excursion documented in the "Summary and Analysis of Area (b) (4) Environment and Gowning Data for May 2017". Your firm then confirmed that no IFR had been opened for this incident. Furthermore, it was never clarified why this IFR document documenting an environmental excursion was destroyed and not speciated.
- b) The production schedule for 05/11/2017 with a written instruction stating "date w/ date we are compounding – not date making the record."
- c) The production schedule for 05/11/2017 states "No IFR for black specs on caps". An internal findings report would be an investigation into this event.
- d) Email dated 03/30/2017 stating "I have spoken with (b) (6) about the confusion surrounding back dating and missing information."
- e) Numerous original documentation, including "Non-Controlled Concentrate Container Accountability Form", "Labeling and Bagging Form Area", (b) (4) Differential Pressure Readings", "Filling Check Weights".
- f) For Lot 10347 (Rocuronium Bromide 10 mg/ml) on document titled "Documentation/Communication of Issues That Arise During the Labeling Process" the following was recorded: "(b) (4) was 1 syringe under and (b) (4) was 1

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syringe over.” The official batch records, deviations and IFRs are silent to this happening.

- g) Sticky note indicating “(b) (4) – sticking to floor & peeling onto floor”. Room (b) (4) is a floor used for aseptic processing. Your firm has no records showing that a deviation or investigation was opened.

2. Your firm appears to have a practice of altering manufacturing records. We observed the following batch records containing instructions (on sticky notes) to modify their contents:

(a) Batch Record for Neostigmine Methylsulfate 1 mg/ml lot 10355 had four (4) yellow sticky flags instructing an operator to “rewrite”, “writeover” and “Done By” (initial the document in the done by section).

(b) Batch Record for Neostigmine Methylsulfate 1 mg/ml lot 10364 was observed to contain sticky flags throughout instructing to complete the batch record with “N/A”, “Add Initials”, indicating “Wrong Date”, specifying “Writeover on date”, among others.

(c) Batch Record for Succinylcholine Chloride 20 mg/ml lot 10376 was observed to contain sticky flags throughout instructing to “cross out”, “wrong #s” on the batch record, instructing “cross out entries that do not apply”, specifying “Writeover on date”, among others.

(d) Batch Record for Rocuronium Bromide lot 10382 was observed to contain sticky flags throughout instructing to “For when you verified lot #” (in “Check By:” Section) and to indicate lot numbers.

This practice is not consistent with contemporaneous batch record completion, in accordance to your firm’s SOP P&P No. 2.120 (R0) titled “Good Documentation Practices” that specifies “Documentation should be completed at the time of occurrence, action, observation, interaction or intervention or documented in such a manner to denote the actual time, date and outcome as soon as possible.”

3. We discovered the following “weight checks” (testing data) that display anomalies:

- a) For the Ephedrine Sulfate 50 mg/ml lot 10331: the “Initial and Delivered Weights for Concentrate Bottles”: The document in the Batch Record is signed and dated “5.26.17”. A

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similar document with identical numbers was found in a shred bin, but dated "6.12.17". This dating discrepancy was not clarified.

- b) For the Sodium Bicarbonate lot 10408: The document in the Batch Record is signed at time "2227". A similar document with identical numbers was found in a shred bin signed at time "2220". This timing discrepancy was not clarified.
- c) For the Sodium Bicarbonate lot 10402: the "Initial and Delivered Weights for Concentrate Bottles": In the shred bin, we observed two versions of this document; however, a different operator signed the version included in the official Batch Record.

**OBSERVATION 3**

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

1. Your firm's anterooms to ISO 7 Cleanrooms (b) (4) demonstrate loss of positive differential pressures (or negative pressures) from the cleanroom to the ISO 7 anteroom (based on an Evaluation from December 2016 to June 2017). The pressure differentials demonstrate that your firm fails to maintain a positive airflow from the cleanroom to the anteroom, assuring appropriate air quality. From reviewing data for the past 6 months, we identified the following extremes in pressure differentials:

Pressure Probe	Associate Cleanroom	Lower Pressure Limit	Upper Pressure Limit	Lowest Observed Pressure	Highest Observed Pressure
<b>(b) (4)</b>					

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**(b) (4)**

SOP P&P No. 3.010 (R6) titled "Temperature, Humidity, Pressure Differential Monitoring of the Classified and Controlled Areas" states "Pressure differentials shall (b) (4) pressure."

**This is a repeat observation from the last FDA inspection conducted 10/14/16.**

Examples of product aseptically processed during pressure loss or a negative pressure between the cleanroom and anteroom includes:

(a) Airflow out of the clean room, which was measured by differential pressure, went negative during manufacture of the sterile products. The measurement of differential pressure at your firm is recorded to ensure air is flowing out of the cleanroom to the corresponding anteroom. In these situations, airflow was recorded as moving from the anteroom into the cleanroom. Examples include:

- i. (b) (4) – Neostigmine 1mg lot 9367
- ii. (b) (4) – Phenylephrine 100mcg lot 9404
- iii. (b) (4) – Ephedrine 10mg lot 9397
- iv. (b) (4) – Neostigmine 1mg lot 9379
- v. (b) (4) – Succinylcholine 20mg lot 9737
- vi. (b) (4) – Succinylcholine 20mg lot 9731
- vii. (b) (4) – Succinylcholine 20mg lot 9735
- viii. (b) (4) – Succinylcholine 20mg lot 9682
- ix. (b) (4) – Adenosine 3mg lot 9567
- x. (b) (4) – Ephedrine 50mg lot 9546
- xi. (b) (4) – Adenosine 3mg lot 9542

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All lots were distributed. The impact of these differential pressure failures on sterile drug products has not been investigated.

(b) (4) Airflow out of the clean room, which was measured by differential pressure, was (b) (4) during manufacture of the sterile products. The measurement of differential pressure at your firm is recorded to ensure air is flowing out of the cleanroom to the corresponding anteroom. Examples include:

- i. (b) (4) – Neostigmine 1mg lot 9543
- ii. (b) (4) – Sodium Bicarbonate Concentrate lot 10402
- iii. (b) (4) – Succinylcholine 20mg lot 10398
- iv. (b) (4) – Neostigmine 1mg lot 9643

All lots were distributed. The impact of these pressure failures on sterile drug products has not been investigated.

2. Further, issues pertaining to cleanroom design are presented below:

a. The ceiling tiles in your ISO 7 clean room (b) (4) contained approximately ¼”- ½” gaps around the HEPA filters.

**This is a repeat observation from the last FDA inspection conducted 10/14/16.**

b. Cracks were observed in the center of the plexiglass siding of ISO 5 Hoods in ISO 7 clean room (b) (4). Aseptic processing occurs in this area.

c. The ISO 7 Anterooms (b) (4) each contain a ceiling HEPA filter adjacent to a ceiling return which has the potential to impede air flow.

d. The ISO 7 classified cleanrooms (b) (4) have HEPA filters located directly above the ISO 5 hoods which has the potential to impede air flow.

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**OBSERVATION 4**

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.

1. Specifically, your firm documented known environmental excursions and failed to conduct an investigation to determine a root cause or assess the impact to products intended for sterile use. The following products were produced during periods of known environmental excursions. For Example:

Date Made	Product Name	Lot	Room Number	Hood Number	ISO 5 CFUs (specification) <sup>(b)(4)</sup>
5/12/2017	SODIUM BICARBONATE 8.4% INJECTION SOLUTION 50 ML SYRINGE	10204	<b>(b) (4)</b>	<b>(4)</b>	<b>(4)</b>
3/16/2017	GLYCOPYRROLATE 0.2 MG/ML INJECTION SOLUTION 5 ML SYRINGE	9801			
1/27/2017	PHENYLEPHRINE HCL 100 MCG/ML IN 0.9% SODIUM CHLORIDE 10 ML SYRINGE	9556			
1/27/2017	LIDOCAINE HCL 2% INJECTION SOLUTION 5 ML SYRINGE	9558			

\*Designates results reflect previous specification set forth in P&P No. 7.230 (8) titled “Environmental Monitoring Program for Area <sup>(b)(4)</sup>” where specifications for an ISO 5 contact area was <sup>(b)(4)</sup> CFU until 03/27/2017.

2. <sup>(b)(4)</sup> utilized by your firm to ensure drug product sterility exhibited the following System and User Abort events that had not been investigated, but the products that were the subject of the events were subsequently retested and released:

- a) 2/24/2017 – Sterility testing of Calcium Chloride lot 170408 was subject to a “USER ABORTED” event. Subsequently, this same lot was retested.
- b) 3/29/17 – Sterility testing of Sodium Bicarbonate lot 10176 was subject to a “USER ABORTED” event. Subsequently, this same lot was retested.
- c) 3/16/17 – Sterility testing of Glycopyrrolate lot 9783 was subject to a “SYSTEM ABORTED” event. Subsequently, this same lot was retested.

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3. Your firm failed to perform an investigation after (b) (4) ISO 5 Hoods which were identified with HEPA filter leaks during re-certification in (b) (4) . From August to November of 2016, these hoods were utilized for aseptic processing; however, your firm failed to conduct a retrospective investigation into product impact. For example,

Hood Identification	Date Leak Reported	Date Leak Corrected	Last Certification with no Leaks
<b>(b) (4)</b>			

**OBSERVATION 5**

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

1. From your firm's (b) (4) recordings on 6/6/17, it was observed that your firm produced Sodium Bicarbonate in Hood (b) (4) (Room (b) (4) Hood (b) (4) During this time, the operator's head was in the hood during cleaning (prior to production) as well as during production of Sodium Bicarbonate 8.4% Injection Solution 50mL Syringes, lot 10377. This exact batch was the subject of the colony observed on agar plate (environmental monitoring) labeled as "(b) (4)" of "(b) (4) Hood (b) (4) dated "6/6" that was discarded without recording on the (b) (4) worksheet or conducting a corresponding investigation. See Observation 1.

For Example:

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Via (b) (4), we observed that on 6/6/2017 in Hood (b) (4) (Room (b) (4) Hood (b) (4) the following poor aseptic practices were utilized:

- a) At 07:06, your operator's upper torso and head were observed in the ISO 5 classified hood during pre-production cleaning.
- b) At 08:01, your operator's head was in the ISO 5 classified hood during aseptic production.
- c) At 09:52, your operator's head was in the ISO 5 classified hood during aseptic production.

2. In addition, your media fill does not appear to simulate the most complicated process of production. Your media fill protocol Aseptic Processing Simulation Protocol (P&P No 4.263) simulates the process (b) (4) However, your firm routinely (b) (4) used for (b) (4)

For example,

Calcium Chloride 10% Concentrate lot 157520 was utilized for aseptic processing of (b) (4) from (b) (4).

Norepinephrine Bitartrate lot 9162 was utilized for aseptic processing of (b) (4) from (b) (4) (b) (4).

Glycopyrrolate lot 9769 was utilized for aseptic processing of (b) (4) from (b) (4).

**This is a repeat observation from the last FDA inspection conducted 10/14/16.**

**OBSERVATION 6**

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

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1. Your firm has not established an approved standard operating procedure (SOP) for (b) (4) clean to include when it is performed, how it is performed, and the reason performed. Your Interim QA/QC director stated (b) (4) cleans are performed (b) (4) (b) (4). However, there were no (b) (4) cleans documented for (b) (4) (b) (4) recorded in environmental monitoring (b) (4) summaries – approximately (b) (4) dates with a cumulative amount of approximately (b) (4) products produced. No investigation was conducted to determine a root cause or assess the impact to products intended for sterile use. The product was released.

2. Routine use of (b) (4) for (b) (4) cleaning with a contact time of (b) (4) ; however, per the manufacturer’s instruction for use a (b) (4) (b) (4) Your routine use of (b) (4) is with a contact time of (b) (4) however, per the manufacturer’s instruction for use a (b) (4) (b) (4) Additionally, your firm fails to document these contact times, which limits verification of cleaning contact times. Speciation results from your contract laboratory (b) (4) indicated the following spore-forming bacteria were present:

Date	Location	Species
4/18/17	ISO 7 Room (b) (4) Air	Paenibacillus taiwanensis
4/17/17	Operator glove	Bacillus circulans
4/7/17	Operator glove	Paenibacillus provencensis
3/21/17	Operator glove	Bacillus cereus
3/17/17	Operator glove	Bacillus amyloliquefaciens / methylophilicus / siamensis
3/15/17	Operator glove	Bacillus pumilus / safensis

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1/30/17	Operator glove	Bacillus circulans
1/25/17	Operator glove	Bacillus aryabhata
1/20/17	Operator glove	Bacillus idriensis
1/11/17	Operator glove	Paenibacillus lautus
1/5/17	Operator glove	Kroppenstedtia eburnean
1/3/17	Operator glove	Sporosarcina luteola
12/15/16	ISO 7 Room <sup>(b) (4)</sup> Keyboard	Bacillus lentus
12/15/16	Operator glove	Ornithinibacillus scapharcae
12/14/16	Operator glove	Psychrobacillus insolitus
12/7/16	ISO 5 Hood <sup>(b) (4)</sup>	Bacillus cereus
11/30/16	Operator Forearm	Bacillus cereus

**This is a repeat observation from the last FDA inspection conducted 10/14/16.**

**OBSERVATION 7**

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

Endotoxin amount in the drug products was not tested throughout the shelf life in the stability studies. For example,

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**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 6/12/2017-6/29/2017*
	FEI NUMBER 3004483441

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
Mr. James L. McCarley , CEO

FIRM NAME Cantrell Drug Company	STREET ADDRESS 7321 Cantrell Rd
CITY, STATE, ZIP CODE, COUNTRY Little Rock, AR 72207-4144	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

- a. Stability studies for Adenosine Injection in 0.9% NaCl 90mg/ml (3 mg/mL), Diltiazem HCl 125 mg in 125 mL bags, and Lidocaine HCl 2% Preservative Free 5 mL syringe did not have endotoxin test during the shelf life.
- b. Stability studies for Glycopyrrolate 0.2 mg\_mL 5 mL syringes only had endotoxin test on day (b) (4) the product is given beyond use date of 135 days.
- c. Your communication with your contract lab showed that you did not plan to conduct endotoxin test for Lidocaine HCl 2% Preservative Free 5 mL syringe for stability study

**OBSERVATION 8**

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

The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A). Specifically, the following information is not found on your drug product labels:

- a) The statement "This is a compounded drug."  
Example(s) of drug product labels that do not contain this information:
  - Glycopyrrolate 0.2 mg/1 mL Injection Solution 5 mL
  - Ephedrine Sulfate in 0.9% Sodium Chloride 5 mL
  - Neostigmine Methylsulfate 5mg/5 mL Injection Solution 5 mL

**This is a repeat observation from the last FDA inspection conducted 10/14/16.**

**\*DATES OF INSPECTION**

6/12/2017(Mon),6/13/2017(Tue),6/14/2017(Wed),6/15/2017(Thu),6/16/2017(Fri),6/29/2017(Thu)

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6/29/2017

**X** Latorie S Jones

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Latorie S Jones  
Investigator  
Signed by: Latorie S. Jones -5

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