DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US FDA, 22215 26th Avenue SE, Suite 210 Bothell, WA 98021 (425) 302-0340 Industry Information: www.fda.gov/oc/industry	4/28/15 to 5/8/15
	FEI NUMBER 3011412185

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Roy "Tim" G. Calcagno, Pharmacist Owner

FIRM NAME	STREET ADDRESS
Montana Compounding Pharmacy and Wellness Center	111 N. Higgins
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Missoula, MT 59802	Producer of Sterile Drug Products

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1

Each lot of a drug component that is liable to microbiological contamination that is objectionable in view of its intended use is not subjected to microbiological tests before use.

Specifically,

A) Raw materials were reported to be reviewed and accepted for use only on review of the Certificate of Analysis (C of A), and not all C of A were available for the raw material or were retained by this producer of sterile drug products. The pharmacist/owner stated that components used to create sterile finished products are not subjected to analytical, sterility or endotoxin tests before use in the formulation of stock solutions or drug products. The pharmacist/owner stated he does not perform any testing of any component materials, including materials which have not been demonstrated as suitable for pharmaceutical use. Four of (b) (4) raw materials C of As, or product quality information, were not available at the firm when the documentation showing raw material quality was requested.

1) (b) (4) (non-sterile; Lot # "unknown") was used to formulate (b) (4) (b) (4) (b) (4) was used to formulate hyaluronidase 10 mL 150 u/mL ("office use" Rx (b) (6) ; Lot # 02272015:93@1), a sterile injectable product. (b) (4) (sold as (b) (4)), obtained from a top-loaded 5-gallon bottled water dispenser in the kitchen area, was not tested by the firm after dispensing to confirm the chemical purity or microbial content was suitable for the intended use in formulating a sterile injectable product. There is no routine maintenance procedure for the water dispenser, the pharmacist/owner stated he (b) (4) the dispenser when it looks like it needs disinfection.

2) Non-sterile, non-pharmaceutical grade (b) (4) (b) (4) brand, non-sterile; Lot # (b) (4)),

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is used as a component of Alprostadil (PGE1) [redacted](b) (4), which is used to prepare finished-product "Trimix" (Rx #(b) (6) Lot #03112015:17@5). "Trimix" is purported to be a sterile injectable; however, the pharmacist/owner conducts no analytical or microbial testing of any of the "Trimix" components before use. For example, the non-sterile, non-pharmaceutical grade (b) (4) ((b) (4) brand) is not tested to confirm identity or chemical purity that would demonstrate pharmaceutical grade equivalence. The non-pharmaceutical grade (b) (4) is not tested for sterility or endotoxins before use to formulate a sterile drug product.

3) Phentolamine (b) (4) (b) (4) (non-sterile; Lot # (b) (4) was used to formulate phentolamine/ papaverine [redacted](b) (4) which is a component of "Trimix" (Rx (b) (6) Lot #03112015:17@5), sold as a sterile injectable. There is no firm sterility or endotoxin testing of the raw material phentolamine (b) (4); and there is no endotoxin testing of the drug product "Trimix."

B) Components of Hyaluronidase and "Trimix", dispensed by prescription as a human sterile injection, are not tested by the firm to assure the raw materials are suitable for use in the formulation of sterile drug products, or the drug products using non-sterile components are not tested for sterility and endotoxin. There are no raw material retention samples for components used in formulation of human drug products.

1) There is no assurance that the (b) (4), used as a component in Hyaluronidase, is suitable for use in the formulation of a sterile ophthalmic injection. (b) (4), used for stock solution formulation, was dispensed through a drinking water dispenser that has no routine maintenance and is not tested to detect the presence of biofilm. (b) (4) was used in the (b) (4) of (b) (4) which was used in the production of Hyaluronidase, Lot 02272015:93@1. Hyaluronidase, Lot 02272015:93@1 was distributed through prescription no. (b) (6)

2) There is no Certificate of Analysis (C of A) or analytical testing for purity, chemical composition or sterility to assure that (b) (4) brand non-sterile (b) (4) (b) (4) is suitable for drug formation. (b) (4) brand non-sterile (b) (4), Lot (b) (4) was used as a component in the production of (b) (4) Alprostadil (PGE1), (b) (4) (b) (4) Alprostadil (PGE1), (b) (4) was subsequently used in the formulation of "Trimix" Lot 03112015:17@5 on March 11, 2015 that was dispensed though prescription no. (b) (6) on March 27, 2015. (b) (4) brand non-sterile (b) (4) is also used in

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the formulation of drug products including but not limited to Tri-Est Progesterone and Cyproheptadine.

3) There is no C of A and no analytical testing on (b) (4), Lot (b) (4) used in the production of a (b) (4) to produce Trimix, Lot 03112015:17@5. Trimix, Lot 03112015:17@5 was dispensed though prescription no. (b) (6) on March 27, 2015.

4) There is no C of A and no analytical testing on (b) (4) Lot (b) (4) used in a (b) (4) for Hyaluronidase, Lot 02272015:93@1. Hyaluronidase, Lot 02272015:93@1 was dispensed through prescription no. (b) (6)

5) The C of A for the components of "Trimix" including Aprostadil USP, Lot (b) (4) Phentolamine (b) (4), Lot (b) (4) Papaverine (b) (4), Lot (b) (4) (b) (4), Lot (b) (4) (b) (4) Lot (b) (4) do not indicate that these components are sterile. Prescription no. (b) (6) containing aforementioned components in "Trimix", Lot 03112015:17@5 was distributed without endotoxin testing.

6) The C of As for the components of Hyaluronidase including Hyaluronidase, (b) (4), Lot (b) (4) and (b) (4), Lot (b) (4) do not indicate if the raw materials are sterile. Prescription no. (b) (6) for Hyaluronidase, lot 02272015:93@1 consisting of Hyaluronidase, Lot (b) (4) and (b) (4), Lot (b) (4) was distributed without sterility or endotoxin testing.

OBSERVATION 2

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

Specifically,

A) There was no qualification to demonstrate the ISO 5 laminar air flow (LAF) area has the physical or procedural controls to perform aseptic formulation operations. No media fill studies were performed to demonstrate the ISO 5 LAF area is suitable for aseptic process operations. No smoke studies have been performed

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to demonstrate laminar air flow in the ISO 5 area during production conditions.

B) The pharmacist/owner has not been aseptic operator qualified by consistently demonstrating successful performance of aseptic operations using growth media to simulate the aseptic operations.

C) There are no written acceptance criteria for the (b) (4) for the (b) (4) test for sterile stock solutions and sterile drug products.

OBSERVATION 3

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

Specifically,

No HEPA leak tests were performed as part of the "Certificate of Inspection" for the custom-built ISO 7 and ISO 8 clean room areas on 10/11/13, 4/4/14, 10/8/14, and 4/6/15. The ISO 7 and ISO 8 clean room areas have no pre-determined acceptance criteria for at least flow rate or room air changes to demonstrate adequate air movement. Smoke studies were not done for the custom-built ISO 7 and ISO 8 clean room areas to establish critical air flow control specifications or to demonstrate the construction and installation of the cleanrooms provide the physical controls to prevent the introduction of microbes and particulates in the ISO 5 LAF area. There is no written acceptance criteria for the pressure cascade between the ISO 7 and the ISO 8 clean room areas. There are no performance checks to demonstrate physical control for microbial and particulate contamination under dynamic conditions in the ISO 7 and ISO 8 clean room areas.

OBSERVATION 4

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

Specifically,

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A) There are no written cleaning procedures and no cleaning documentation for the ISO 5 LAF area, and the ISO 7 and ISO 8 clean room areas used for aseptic repackaging, aseptic formulation of stock solutions and formulation of sterile drug products. There is no procedure describing the preparation of (b) (4) used for disinfecting the ISO 7 and ISO 8 clean room areas. There is no established practice to clean the ISO 5 LAF area, and the ISO 7 and ISO 8 clean room areas. The pharmacist/owner said he is still "tweaking" the cleaning process to be able to clean all surfaces without working over a previously cleaned area. The cleaning process has been conducted with non-sterile hand held wipes, and non-sterile wipes affixed to the long-handled wipe holder used to clean the ceiling, wall, and floor.

B) On 4/28/15 and 4/29/15, we observed the ISO 5 LAF area being cleaned before and after use with non-sterile wipes moistened with sterile (b) (4). There is no documentation to verify a sporicidal agent has been used to clean the ISO 5 LAF area, and there was no use of a sporicidal agent in the ISO 5 LAF area cleaning we observed.

OBSERVATION 5

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

Specifically,

A) Both the (b) (4) "Certificate of Inspection" for the ISO 5 LAF area reads in part "*** Low airflow. Increase motor speed to max to obtain nominal setpoints. New HEPA filter needed ***." After becoming aware of the need to change the HEPA filters, the pharmacist/owner said he (b) (4) There are no performance checks to demonstrate physical control for microbial and particulate contamination under dynamic conditions in the ISO 5 LAF area.

B) There is no ISO 5 LAF HEPA filter (b) (4) procedure consistent with the (b) (4) user's manual which reads in part (b) (4)

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(b) (4) ". The pharmacist/owner (b) (4) the ISO 5 LAF area (b) (4) (b) (4), and only disinfects the work area with a non-sterile wipe moistened with (b) (4). The pharmacist/owner said the ISO 5 LAF HEPA is (b) (4) The last two ISO 5 certifications, on (b) (4) read in part "*** Low airflow. Increase motor speed to max to obtain nominal setpoints. New HEPA filter needed ***."

OBSERVATION 6

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

Specifically,

A) There is no environmental monitoring data to demonstrate the ISO 5 LAF area, and the ISO 7 and ISO 8 clean rooms have physical and procedural controls suitable for the intended use of formulating sterile stock solutions and sterile drug products. The ISO 5 LAF area, and the ISO 7 and ISO 8 clean rooms were reported to have been installed October 2013.

B) The pharmacist/owner said there is no environmental monitoring program to demonstrate the physical and procedural controls are adequate during actual conditions of use to formulate sterile stock solutions and sterile drug products.

OBSERVATION 7

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

Specifically, protective apparel items used for aseptic formulation operations were not sterile, were not worn as necessary, and some items were reused. The following gown items are not sterile initially, and are stored on the rack in the ISO 8 area to be re-used: lab coat, shoe covers, and facemask. The non-sterile hair cover and gloves are single use. The yellow sleeve covers were re-used. Only the non-sterile gloves and the re-used sleeve covers were disinfected with sterile (b) (4).

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A) On 4/28/15, an Avastin 100mg 25 mg/mL single use vial (manufacturer's Lot (b) (4) was repackaged into (b) (4) syringes, designated as Lot 04232015:16@13. We observed the pharmacist/owner gown into what appeared to be previously used shoes with shoe covers, a lab coat on a hanger, a face mask hung on the shelf unit, and yellow sleeve covers from the shelf unit in the ISO 8 area. After repackaging operations, these gown items were returned to the shelf unit and shoes with covers were returned to the floor in the ISO 8 area. The pharmacist/owner said the gown items are re-used and are changed at a frequency he estimated to be (b) (4) The pharmacist/owner said he used non-sterile gloves, and decontaminated the gloves and re-used yellow sleeve covers with sterile (b) (4) . Exposed skin and beard were seen at the sides of the face mask held in place using only one of two bands when he was working at the ISO 5 LAF work area.

B) On 4/29/15, Phentolamine/papaverine (b) (4) was formulated as Lot (b) (4) We observed the pharmacist/owner gown into previously used gown items, however he failed to don a hair cover before entering into the ISO 7 area to (b) (4) the ISO 5 LAF HEPA unit (b) (4). While he was wiping the ISO 5 work area, we observed him with exposed skin, beard, and the hair of his uncovered head pass into the ISO 5 LAF area.

OBSERVATION 8

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

Specifically,

A) The pharmacist/owner said the facility was not designed or evaluated with the objective to prevent the introduction of microbes and particulates into the areas adjacent to the ISO 5 LAF area where sterile drug products are formulated, and ISO 7 and ISO 8 clean room areas. No survey of the pharmacy and co-owned wellness center was conducted to determine potential sources of microbial and particulate contamination in the proximity of the clean room. An apparently dusty building air duct exhausts directly over the ISO 7 and ISO 8 clean room areas containing the ISO 5 LAF area. The retail area of the pharmacy is carpeted. The ceiling panels are porous and there is no assurance the panels do not shed particles to the area immediately adjacent to the clean room. During the work day, we observed personnel moving between the sidewalk-level pharmacy and the lower level wellness

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center. On the carpeted lower level at the bottom of the carpeted stairs is a desk, behind the desk are black portable fence panels and an apparent pet bed. The co-owner said at times her dogs are brought to the facility. Both the lower level black portable fence panels and pet bed, and the ISO 7 and ISO 8 clean room areas containing the ISO 5 LAF area where sterile drug products are formulated, can be seen in one photo image taken 5/1/15. There has been no assessment performed regarding the presence of dogs and shed hair, and the impact on the quality of the clean room.

B) On 5/1/15, the (b) (4) cleaning of the pharmacy and wellness center was partially observed being performed by a contracted service provider, (b) (4), using an apparent household vacuum in the pharmacy formulation area immediately adjacent to the ISO 7 and ISO 8 cleanroom. (b) (4), (b) (6) Supervisor said (b) (6) cleans the (b) (4). (b) (4), (b) stated (b) (6) changed the (b) (4). The vacuum bag was visibly full when the vacuum was opened for inspection. The rotating floor brush of the vacuum was observed to have apparent dust residue on the bar and in the brush.

OBSERVATION 9

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

Specifically, the firm has no written stability program to establish the Beyond Use Date (BUD) for at least the formulated sterile drug products. The pharmacist/owner said he used the BUDs estimated in the software used to generate the Logged Formula Worksheet; however on review, not all the stock solution or drug product BUDs were consistent with the estimated BUDs. Further, not all Logged Formula Worksheets contained estimated BUDs. The following deficiencies were detected in review of sterile drug stock solutions and sterile drug products:

A) There is no written stability program to establish BUDs for Logged Formula Worksheets without estimated BUDs. As a representative example: Hyaluronidase 10 mL 150 U/mL injection, Lot 02272015:93@1, was given a BUD 100 "days after compounding date" without scientific data.

B) There is no written stability program to extend the BUDs for Logged Formula Worksheets without software estimated BUDS. As a representative example: Avastin 1.25 mg/0.05 mL syringe Lot 08262014:16@4, batch

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yield (b) (4) was given a BUD of 30 "days after compounding date". Avastin 1.25 mg/0.05 mL syringe Lot 04282015:16@3, batch yield (b) (4) was given a BUD of 45 "days after compounding date". No scientific data was provided for the establishment of the Avastin BUD of 30 days when repackaging a single use vial into (b) (4) syringes, or for the extension of the Avastin BUD to 45 days for the same repackaging operation.

C) The pharmacist/owner said there is no study for sterility beyond the use date.

D) The pharmacist/owner said there is no study for potency beyond the use date.

E) The pharmacist/owner said there is no study to determine if the antimicrobial properties of preserved solutions retain these properties beyond the use date.

OBSERVATION 10

Test procedures relative to appropriate laboratory testing for sterility and pyrogens are not written.

Specifically,

A) The firm uses the (b) (4) test method for sterility assurance, however there are no test method suitability studies for the (b) (4) test method used by the firm for: Avastin1.25 mg single use vial repackaged into 0.05 mL syringes; "Trimix" (alprostadil/phentolamine/papaverine) injection; and (b) (4) vehicle for injection (the hyaluronidase injection vehicle).

B) The following representative injectable drug products were not tested for sterility or endotoxin:

1) Hyaluronidase 10 mL 150 U/mL injection Lot 02272015:93@1; with a beyond use date (BUD) of 100days after compounding that is not based on scientific data; and formulated with Hyaluronidase (b) (4) [redacted] that has no sterility or endotoxin testing reported on the C of A for raw material lot (b) (4) [redacted]

2) Alprostadil (PGE1) 20ug/mL injection Lot 04022015:93@10; with a BUD of 120 days after compounding that is not based on scientific data.

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3) "Bimix" (phentolamine/papaverine) (10/300) 1-30 mg/mL; with a BUD of 180 days after compounding that is not based on scientific data. The pharmacist/owner said the phentolamine raw material and papaverine raw material are not sterile.

4) Phenol aqueous 7% injection "*** For Office Use ***" Lot 02062015:86@4; with a BUD of 7 days.

5) Phentolamine/papaverine 0.5 mg/30mg/mL injection Lot 03042015:02@7; with a BUD of 45 days that is not based on scientific data. The pharmacist/owner said the phentolamine raw material and papaverine raw material are not sterile.

C) The following representative ophthalmic drug products were not tested for sterility:

1) Interferon (Intron A) ophthalmic solution eye drops Lot 03052015:23@19; with a BUD of 30 "days after compounding date". The BUD exceeds the software estimated BUD of 24 hours at RT or 3 days if refrigerated, and there is no scientific data to support the 30 day BUD.

2) Glutathione-ascorbic acid 1.25-1% ophthalmic solution Lot 04092015:10@13; with a BUD 30 "days after compounding date". There is no scientific data to support the 30 day BUD.

D) The following representative drug products labeled sterile were not tested for sterility:

1) Phenylephrine HCl Sterile 1.5% solution Lot 03242015:18@1; with a BUD 5 "days after compounding date". There is no scientific data to support the 5 day BUD.

2) "Sterile" acetic acid iontophoresis 5% (W/V) Solution Lot 02182015:52@12; with a BUD 30 days after compounding which exceeds the software estimated 24 hrs at RT.

E) There are no controls for the number of times a stock solution vial can be entered to withdraw the material for formulation in a sterile drug product.

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OBSERVATION 11

Written procedures are lacking which describe in sufficient detail the receipt, identification, storage, handling, sampling, testing, approval, and rejection of components, drug product containers, and closures.

Specifically,

There is no written procedure describing the receipt of components and container closure systems used for production of drug products including, but not limited to, sterile drugs Avastin, Hyaluronidase, and "Trimix."

OBSERVATION 12

Components for drug product manufacturing are not weighed as appropriate.

Specifically, on 4/29/15, we observed the formulation of phentolamine/papaverine (b) (4) (b) (4) (b) (4). During the aseptic formulation, the entire contents of an unopened bottle of phentolamine (b) (4) (b) (4) (b) (4) was used for the formulation. The pharmacist/owner said the contents of the unopened bottle was not weighed prior to formulation, and that he uses the practice to (b) (4) during aseptic process formulations. The pharmacist/owner said there was no chemical analysis of the (b) (4) and said there would be no chemical analysis of the finished product that used the (b) (4). When we asked how the potency of the finished drug product was said, the pharmacist/owner said potency was only calculated based on the labeled weight of the unopened stock bottle.

OBSERVATION 13

Routine calibration of mechanical equipment is not performed according to a written program designed to assure proper performance.

Specifically,

A) There has been no periodic calibration of the (b) (4) balances used to determine the weight of solid raw materials

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DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US FDA, 22215 26th Avenue SE, Suite 210 Bothell, WA 98021 (425) 302-0340 Industry Information: www.fda.gov/oc/industry	4/28/15 to 5/8/15
	FEI NUMBER 3011412185

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Roy "Tim" G. Calcagno, Pharmacist Owner

FIRM NAME	STREET ADDRESS
Montana Compounding Pharmacy and Wellness Center	111 N. Higgins
CITY, STATE AND ZIP CODE Missoula, MT 59802	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile Drug Products

used in formulations: (b) (4) [redacted] The pharmacist/owner said the firm relies on the internal calibration; there is no assurance the internal calibration system is functional.

B) There has been no calibration of the air pressure gauge used to perform the (b) (4) [redacted]

OBSERVATION 14

Batch production and control records do not include complete information relating to the production and control of each batch.

Specifically,

A) Formulation record "Logged Formula Worksheet" for the production of Hyaluronidase and "Trimix" do not document the results of sterilizing (b) (4) [redacted], do not contain a specimen of the label for working solutions, and a statement of actual yield and theoretical yield.

B) Formulation record "Logged Formula Worksheet" do not always include the actual label of the (b) (4) [redacted] as evident in (b) (4) Phentolamine/Papaverine (b) (4), Lot (b) (4) and (b) (4) (b) (4) [redacted] (b) (4). When a (b) (4) label is retained, the lot and expiry of the (b) (4) do not always match the material stated in the "Logged Formula Worksheet" as evident in the production record such as (b) (4) Phentolamine/Papaverine, Lot (b) (4) and (b) (4) Alprostadil (PGE1), (b) (4) [redacted]

C) Formulation record "Logged Formula Worksheet" for the formulation of Hyaluronidase and "Trimix" do not always include the weights and measures of components in the formulation; the identification of product contact surfaces such as vent needle and septum seal applied after formulation; or the bar code verification check of components used in formulation.

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OBSERVATION 15

Procedures describing the handling of all written and oral complaints regarding a drug product are not established.

Specifically, there are no written procedures for the management of complaints or the management of adverse events for the drug products distributed by the firm. Additionally, a complaint file is not maintained at the firm.

OBSERVATION 16

Batch production and control records do not include dates of each significant step in the manufacture and processing of the batch for each batch of drug product produced.

Specifically,

Specifically, there is no assurance that "date made" is always the actual date of production on the production record "Logged Formula Worksheet." The production of [redacted] (b) (4) Phentolamine/Papaverine [redacted] (b) (4) [redacted] for Trimix was observed on April 29, 2015, however, the "date made" is listed on the "Logged Formula Worksheet" as April 28, 2015.

OBSERVATION 17

Equipment and utensils are not cleaned, maintained, and sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically, on 5/1/15, a syringe reported to be used for measuring non-sterile, non-pharmaceutical grade [redacted] (b) (4) brand) for production of drug products such as "Trimix" was observed secured to the [redacted] (b) (4) bottle with a rubber band. There was no label on the syringe to prevent a mix-up in using the dispensing aid for different components. There is no control on the number of uses or duration a syringe is used to

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ensure the [redacted] (b) (4) contact surface is not additive, absorptive, leachable, or otherwise impacts the quality of the component. Securing a syringe to a component, to be re-used to measure the component, is a common practice at the firm as identical syringes were observed to be secured with a rubber band to bottles holding [redacted] (b) (4) [redacted] (b) (4) [redacted] (b) (4)

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5/8/15

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