

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417		<small>DATE(S) OF INSPECTION</small> 9/12/2018-9/27/2018* <small>FEI NUMBER</small> 3013316698			
<small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small> Amy L. Summers, Pharm.D., Pharmacist In Charge					
<small>FIRM NAME</small> MedisourceRx		<small>STREET ADDRESS</small> 10525 Humbolt St			
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Los Alamitos, CA 90720-5401		<small>TYPE ESTABLISHMENT INSPECTED</small> Outsourcing Facility			
<p>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.</p>					
<p>DURING AN INSPECTION OF YOUR FIRM WE OBSERVED: OBSERVATION 1</p> <p>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.</p> <p>Specifically, there was a failure by your quality control unit to investigate fiber particulates that were found during commercial production of Glutathione 200mg/mL in 30mL MDV and during media fill qualifications. Examples include, but are not limited to, the items listed below.</p> <p>A.) <u>Glutathione 200mg/mL in 30mL MDV</u></p> <ul style="list-style-type: none"> Lot MSRX1207; 13 vials with white fiber particulates found. Lot MSRX1189; three (3) vials with white fiber particulates found. Lot MSRX1181; seven (7) vials with fiber particulates found. <p>B.) <u>Media Fills in February 2018</u></p> <ul style="list-style-type: none"> Fiber particulates found in a total of three (3) vials for media fills performed by Technician (b) (6). Fiber particulates found in a total of six (6) vials for media fills performed by Technician (b) (6). Fiber particulates found in a total of 37 vials for media fills performed by Technician (b) (6). <p>These media fill qualifications for all three (3) Technicians were documented by your firm to have passing results.</p> <p>Additionally, a (b) (4) qualification study has not been performed by your firm. There is no data for the</p>					
SEE REVERSE OF THIS PAGE		<table style="width: 100%; border: none;"> <tr> <td style="width: 60%; border: none; vertical-align: top;"> <small>EMPLOYEE(S) SIGNATURE</small> Stephanie A Slater, Generic Drug User Fee Amendments (GDUFA) Bryan A Galvez, Investigator </td> <td style="width: 40%; border: none; vertical-align: top;"> <div style="text-align: center;"> <small>Stephanie A Slater Generic Drug User Fee Amendments (GDUFA) Signed By: Stephanie A. Slater -S Date Signed: 08-27-2019 16:38:09</small> </div> <div style="text-align: center; margin-top: 10px;"> X </div> </td> </tr> </table>		<small>EMPLOYEE(S) SIGNATURE</small> Stephanie A Slater, Generic Drug User Fee Amendments (GDUFA) Bryan A Galvez, Investigator	<div style="text-align: center;"> <small>Stephanie A Slater Generic Drug User Fee Amendments (GDUFA) Signed By: Stephanie A. Slater -S Date Signed: 08-27-2019 16:38:09</small> </div> <div style="text-align: center; margin-top: 10px;"> X </div>
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compatibility of the (b) (4) used during drug product aseptic fills specifically with the compounded formulation(s) that are produced at your firm.

OBSERVATION 2

Clothing of personnel engaged in the manufacturing, processing, packing and holding of drug products is not appropriate for the duties they perform.

Specifically, we observed a cleaning employee touch their garments on the floor while she was donning sterile gowning. An example includes, but is not limited to, the event listed below.

- On 09/18/2018, we observed (contract) cleaning employee (b) (6) brush the sleeves of her sterile gown (edges of the sleeves on the jumpsuit) on the floor during the gowning procedure in the ISO 8 Gown Room prior to aseptic facility cleaning procedures.

OBSERVATION 3

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

Specifically, we found deficiencies in facility cleaning procedures and records; including, but not limited to, the examples listed below.

A.) On 09/18/2018, we observed cleaning in the ISO 8 classified Hallway and ISO 7 classified Fill Room (b) (4) and Fill Room (b) (4). We observed that the cleaning employees (b) (6) and (b) (6) failed to disinfect cleaning materials/items before the items were transferred from the ISO 8 Hallway into ISO 7 Fill Rooms. Additionally, your SOP titled, "PRS-004, Working in ISO Cleanroom Environments, Revision 02 Effective 04/04/18" does not instruct employees to disinfect items before transferring them from ISO 8 classified areas into ISO 7 classified Fill Rooms.

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B.) Written procedures and records pertaining to aseptic facility cleaning appear deficient. Examples include, but are not limited to, the items listed below.

- SOP titled, "FAC-006, Cleaning of the Cleanroom Revision 03 Effective 05/04/18" does not specify maximum area of mop strokes before employees need to re-saturate mop heads.
- SOP FAC-006 does not specify the direction of which cleaning is to occur within the room (for example, top to bottom, back to front, etc.).
- SOP FAC-006 and your firm's records titled, "Daily, Weekly, Monthly Cleaning Logs" do not specify how the "Daily, Weekly, Monthly Schedule" is completed by employees. There is a schedule that is an attachment to SOP FAC-006 (FAC-FRM-006.002); however, the level of detail specified in this SOP attachment is not documented by the employees. The Quality Assurance Manager stated the schedule is only used as a reference and SOP FAC-006 does not instruct employees to document these details. For example, the equipment located in ISO classified areas that are used in production, and included in facility cleaning, is not documented.
- Disinfectants are supposed to be rotated (b) (4) per SOP FAC-006. However, in the "Disinfectant Used" field of the "Daily, Weekly, Monthly Cleaning Logs", it is unclear which disinfectants were rotated and which disinfectants are used on which date. SOP FAC-006 does not instruct employees to document disinfection rotation.
- "Daily, Weekly, Monthly Cleaning Logs" do not document the required (b) (4) contact time of disinfectants and SOP FAC-006 does not instruct employees to document contact times.
- The lot numbers and expiration dates of cleaning agents are not documented on the "Daily, Weekly, Monthly Cleaning Logs" and SOP FAC-006 does not instruct employees to document this information.

C.) Disinfectant testing effectiveness studies, including plans and reports, have not been completed at your firm.

OBSERVATION 4

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<p>Employees engaged in the manufacture, processing, packing and holding of a drug product lack the training required to perform their assigned functions.</p> <p>Specifically, we observed that employee training records appear deficient in that they lack full details of training content. Examples include, but are not limited to, the items listed below.</p> <p>A.) Your firm documents that employees are trained on SOP "PRS-002 Gowning Procedure Prior to Cleanroom Access" and SOP "PRS-003 Hand Washing Procedure" with names and dates in your "Competency Audit: Gowning and Handwashing" form. However, the record does not state the specification needed to pass and the actual result obtained by the employee.</p> <p>Additionally, there were at least two (2) documented examples of CAPA (Corrective and Preventive Action) Reports where personnel monitoring of gowning during aseptic fill failed specifications.</p> <ul style="list-style-type: none"> • CAPA 18-004: 2 samples exceeded action limit of ^{(b) (4)} CFU. <ul style="list-style-type: none"> ○ Primary Technician Gown Hood on 03/19/2018; result 10 CFU; identified as <i>Rothia dentocariosa</i>. ○ Primary Technician Gown on 05/04/2018; result 4 CFU; identified as <i>Rothia mucilaginosa</i>. • CAPA 18-005: 1 sample exceeded action limit of ^{(b) (4)} CFU. <ul style="list-style-type: none"> ○ Primary Technician Gown on 08/02/2018; result 5 CFU; identified as <i>Streptococcus australis</i>. <p>After the personnel monitoring excursion events dated 05/04/2018 and 08/02/2018, technicians continued commercial drug production.</p> <p>B.) Your firm has used a contract facility cleaning company since January 2018 (or earlier) to perform aseptic facility cleaning procedures. Training records for the contract cleaning employees show that three (3) of the ^{(b) (4)} contract employees did not receive training on the following topics before they were allowed to enter your clean rooms to conduct cleaning operations. We noted the training record</p>							
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dates for the topics of SOP FAC-006 Cleanroom Cleaning; SOP FAC-008 Facility Cleaning; and PRS-002/003 Gowning/Handwashing Procedures.

Cleaning Employee Initials	SOPs; Training Dates at MedisourceRx	First Aseptic Facility Cleaning Date by the Cleaning Employee Shown on MedisourceRx Logs
(b) (6)	FAC-006 and PRS-002/003; 11/03/2017 and 05/18/2018 FAC-006; 05/19/2018 PRS-002/003; 06/13/2018	01/15/2018
(b) (6)	FAC-006 and PRS-002/003; 05/07/2018 FAC-006 and PRS-002/003; 05/16/2018 PRS-002/003; 06/13/2018	05/10/2018
(b) (6)	FAC-006 and PRS-002/003; 06/27/2018 FAC-006 and PRS-002/003; 07/12/2018	02/26/2018
(b) (6)	FAC-006; 05/16/2018 PRS-002/00; 05/18/2018 FAC-006; 05/19/2018 PRS-002/003; 06/21/2018	01/25/2018

OBSERVATION 5

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The control systems necessary to prevent contamination or mix-ups are deficient.

Specifically, on 09/17/2018, we observed within the ISO classified areas, that more than one door can remain open at the same time. Your written procedures, including, but not limited to, the SOPs listed below, do not include instructions to employees to exercise controls to open one door at a time within the ISO classified areas.

- SOP titled, "FAC-001, Facility Design and Process Flow Revision 01 Effective 01/15/18"
- SOP titled, "PRS-004, Working in ISO Cleanroom Environments Revision 02 Effective 04/04/18"

OBSERVATION 6

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

Specifically, we observed that your firm's media fill qualification procedures failed to demonstrate worst-case conditions. The media fill qualification documents (protocol attachments and/or formulation worksheets) from January, February, August, and September 2018 failed to document the items including, but not limited to, the parameters listed below.

- The number of people present in the ISO 7 classified Fill Room at the time of the media fill(s) was not documented to show a worst-case condition of maximum occupants in the room.
- The media fill procedure does not clearly state how the media fill unit incubation results should be documented. For example, (b) (4) readings for all (b) (4) days of media vial incubations to be documented vs. just the final outcome.
- Visual inspection acceptance criteria are not clearly specified in the media fill procedures; for example, the number of vials with fibers or other particulates that would pass or fail a media fill

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lot.

- Item numbers of materials used during media fill qualifications were not documented on the media fill batch records.

OBSERVATION 7

The batch production and control records are deficient in that they do not include documentation of the accomplishment of each significant step in manufacturing, processing, packing and holding.

Specifically, documentation examples include, but are not limited to, the items listed below.

A.) Glutathione 200mg/mL in 30mL MDV Drug Product

1.) On 09/17/2018, we observed technicians documenting batch production records for Glutathione 200mg/mL in 30mL MDV lot MSRX1209. We noted that the technicians do not contemporaneously document full details of the compounding and filling process for this product. Examples include, but are not limited to, the items listed below.

- The execution of each step and verification that the step was completed, such as initials of the Technician and second person after every step.
- (b) (4) not documented.
- (b) (4) times (start and finish) are not documented.
- Values, such as grams of weighed raw materials, are not contemporaneously documented.
- (b) (4) values are written on separate paper and transcribed to batch record.
- Not all item numbers and lot numbers of materials are documented; for example, transfer tubing lot and expiration information is missing on Glutathione product lots MSRX1181 and MSRX1189.

Your SOP titled, "QAU-013, Good Documentation Practices Revision 00 Effective 11/11/16" states in

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section 5.1.2, "Information shall be entered on the original document at the time the work is performed."

B.) Media Fill Qualifications

Like the commercial batch production records noted above, media fill qualification documents and formula worksheets do not fully document the items including, but not limited to, the examples listed below.

- The completion of visual inspection and results are not documented in the August and September 2018 media fill documents and this is not included in the master formula.
- The completion of every step, including verification by a second person that it was completed.
- (b) (4) are not documented.
- (b) (4) times (start and finish) are not documented.

C.) (b) (4) Cycles

Your (b) (4) is validated for use at (b) (4). The (b) (4) log is the only record of when the (b) (4) is run. The log is deficient in that it does not record the time the (b) (4) was operated or when (b) (4) was reached.

Your (b) (4) is validated for use at (b) (4). The (b) (4) log is the only record of when the (b) (4) is run. The log is deficient in that it does not record the time the (b) (4) was operated or when (b) (4) was reached. For example, the time the (b) (4) was operated and when it reached (b) (4) was not recorded for (b) (4) lots 0516201801, 0719201801, 0910201501, and 0913201801. These lots included stir blades, graduated cylinders, forceps, beakers, stainless steel pots, and lids. The items with the four lot numbers above were used in the manufacture of four commercial lots of Glutathione 200mg/mL in 30mL MDV, lot numbers MSRX1181, MSRX1189, MSRX1207, and MSRX1209.

D.) (b) (4) Sterilization Cycles

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Your firm conducts (b) (4) biological indicator (BI) challenges to the (b) (4). The BI challenges are recorded on the BI performance form. The BI performance form is deficient in that it does not record the lot of the BI used during the challenge.

E.) Environmental Monitoring Records

Your firm performs (b) (4) Environmental Monitoring (EM) sampling of the facility and uses "Environmental Monitoring Packet" forms specified by each (b) (4) and (b) (4). The EM documentation is deficient in that the items including, but not limited to the examples listed below, are missing, or unclear.

- Lot numbers are included, but expiration dates are not documented.
- Temperature and duration of settling and contact plates incubations are not clear in the records. The forms do not clearly document the days at which plates are incubated in each temperature condition. According to your SOP, "PPC-002 Cleanroom Environmental Monitoring Revision 01 Effective 12/01/2017":
 - "Settling plates are to be incubated for (b) (4) °C" and
 - Surface and Personnel Contact plates are to be incubated for (b) (4) °C and (b) (4) °C".

***DATES OF INSPECTION**

9/12/2018(Wed), 9/13/2018(Thu), 9/14/2018(Fri), 9/17/2018(Mon), 9/18/2018(Tue), 9/19/2018(Wed), 9/20/2018(Thu), 9/27/2018(Thu)

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