

| DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION | | | |
|---|---|---|--|
| DISTRICT ADDRESS AND PHONE NUMBER 250 Marquette Ave, Ste. 600 Minneapolis, MN 55401 (612) 334-4100 Fax: (612) 334-4134 | | DATE(S) OF INSPECTION 9/10/2018-9/21/2018* | |
| | | FEI NUMBER 3014124016 | |
| NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Bradley M. Phillips, Director of LTC Pharmacy Ops. | | | |
| FIRM NAME Thrifty White Drug #762 | | STREET ADDRESS 6055 Nathan Ln N Ste 200A | |
| CITY, STATE, ZIP CODE, COUNTRY Minneapolis, MN 55442-1675 | | TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-sterile Drug Products | |
| <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> | | | |
| DURING AN INSPECTION OF YOUR FIRM WE OBSERVED: | | | |
| OBSERVATION 1 | | | |
| Sporicidal agents were not used in your facility's cleanrooms and/or ISO 5 classified aseptic processing area. | | | |
| Specifically, on September 10, 2018 we observed your daily cleaning of ISO 5 aseptic processing area was done without the use of any sporicidal agents. We noted that during the cleaning process, (b) (4) was the only agent used. We also noted that there is no sporicidal agent used in the (b) (4) cleaning of the ISO 5 aseptic processing area. Your firm stated no sporicidal agent is used in the ISO 5 aseptic processing area. | | | |
| OBSERVATION 2 | | | |
| Disinfecting agents and cleaning wipes used in the ISO 5 classified aseptic processing areas were not sterile. | | | |
| Specifically, On September 10, 2018, we observed an employee clean the ISO 5 aseptic processing area with (b) (4) and non-sterile wipes before starting aseptic processing of Cefazolin 2gm/100ml Prescription # (b) (6). | | | |
| OBSERVATION 3 | | | |
| Equipment was and Materials or supplies were not disinfected prior to entering the aseptic processing areas. | | | |
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| | | | <small>Anthony J Ladner Investigator Signed By: Anthony J. Ladner -S Date Signed: 09-21-2018 09:17:17</small> X |
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| <p>Specifically, Items are sprayed with (b) (4) in the non-classified area of the pharmacy, then transported to the non-classified (b) (4) which leads directly to the ISO 7 buffer area. These items are then placed into the ISO 5 aseptic processing area without further disinfection.</p> | | | |
| <p>OBSERVATION 4 The ISO 5 classified aseptic processing areas had difficult to clean equipment or surface.</p> <p>Specifically. The back of the ISO-5 aseptic processing area does not have a smooth cleanable surface and it contains (b) (4) which include (b) (4) type surfaces.</p> | | | |
| <p>OBSERVATION 5 ISO 5 classified areas were not certified under dynamic conditions.</p> <p>Specifically,</p> <p>Smoke studies performed in the ISO 5 laminar hood were not performed under dynamic conditions that represent your aseptic processing practices. We observed the aseptic processing of Cefazolin 2gm/100ml Prescription # (b) (6) which included (b) (4) in the ISO 5 hood, using a repeater pump with (b) (4) (b) (4) which were not replicated during the smoke studies. There is no video or description provided of the smoke study and no employees of your firm participated or witnessed the smoke study.</p> | | | |
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| <p>OBSERVATION 6</p> <p>Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.</p> <p>Specifically, Your firm follows the instructions of the (b) (4) media fill kit for risk level-1 (simple procedure) which involved (b) (4) contained in the kit and an (b) (4) provided by your firm. We observed the aseptic processing of Cefazolin 2gm/100ml Prescription # (b) (6) which included (b) (4) in the ISO 5 hood, using a repeater pump with (b) (4) The (b) (4) media fill kit risk level 1 procedure does not simulate the batch size or use of repeater pump and (b) (4) which are part of your firm's routine conditions.</p> | | | |
| *DATES OF INSPECTION 9/10/2018(Mon), 9/11/2018(Tue), 9/12/2018(Wed), 9/20/2018(Thu), 9/21/2018(Fri) | | | |
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| <div style="border: 1px solid black; padding: 5px; margin-bottom: 10px;"> <p> X <small>Ross J Grigsby</small> <small>Investigator</small> Signed By: Ross J. Grigsby -S Date Signed: 09-21-2018 09:18:41 </p> </div> | | |
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