

**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 7/12/2021-8/2/2021*
	FEI NUMBER 3014483112

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Craig E. Else, Director / COO

FIRM NAME IntegraDose Compounding Services LLC	STREET ADDRESS 719 Kasota Ave Se
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CITY, STATE, ZIP CODE, COUNTRY Minneapolis, MN 55414-2842	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

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

Specifically,

-Individual media fills performed by personnel are limited to ^{(b) (4)} vial units and not representative of production quantities and process. For example, Lot ^{(b) (4)}, produced on 7/12/2021, filled and capped approximately ^{(b) (4)} syringes of drug product using a repeater pump.

-On 6/28/21, the ^{(b) (4)} ^{(b) (4)} cleaning was not performed due to an HVAC Discrepancy and later that day production was performed for Cefazolin Lot #'s ^{(b) (4)}. These lots were approved for Final Release by Quality on 7/20/21. This HVAC event was not recorded in the Cleanroom Event Log, therefore not reviewed by the quality unit.

OBSERVATION 2

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

Specifically,

-On 7/19/21, we observed a video from 7/1/21 from room ^{(b) (4)}, an ISO 7 Cleanroom, where a square

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Anthony J Ladner, Investigator Ross J Grigsby, Investigator Kevin P Regan, Investigator	Anthony J Ladner Investigator Signed By: Anthony J. Ladner-03 Date Signed: 08-02-2021 08:08: 6 X	DATE ISSUED 8/2/2021

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on the floor was missed in mopping. Furthermore, in room (b) (4), an ISO 7 Cleanroom, a mop head was used for two squares instead of being changed after each square, as stated in the Cleaning SOP EV-5010 Cleaning Program: 503B Cleanroom Rev. 02 Effective 8/17/20. During these same cleanings, a worker touched the bottom of the dirty mop head with their gloved hand while changing the mop head and did not change gloves nor sanitize gloves, and subsequently touched cart handles, chairs and door handles. The cleaners also used a back-and-forth mopping pattern while mopping the floor as opposed to a figure-8 pattern.

-On 7/19/21 we observed a worker on 7/1/21 spray (b) (4) detergent and (b) (4) for disinfecting on a stainless-steel cart and not wait the designated dwell time to remove the product as stated in the Cleaning SOP EV-5010 Cleaning Program: 503B Cleanroom Rev. 02 Effective 8/17/20.

-On 7/19/21 we observed a compounding technician on 7/2/21 spray (b) (4) and (b) (4) for disinfecting on a stainless-steel cart and not wait the designated dwell time to remove the product as stated in the Cleaning SOP EV-5010 Cleaning Program: 503B Cleanroom Rev. 02 Effective 8/17/20.

During our walk-thru on 7/15/21 we observed the following:

- Apparent rust/corrosion on utility carts used in the ISO 8 area to import supply kits containing IV bags and syringes and shelving used in the ISO 8 area to hold cleaning supplies and sterile wipes as well as a Hepa filter grate and return air grate in room (b) (4).

-What appears to be significant dust build up on the door brush for the (b) (4) overhead door within the ISO-8 area Room (b) (4) where final visual inspection is performed.

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-Black residue on the floor next to the wheel of Hood (b) (4) in the ISO 7 area room (b) (4), and on the floor near the wheels of a storage cart in the ISO 8 room (b) (4).

-White flecks on the floor in several areas of the ISO 8 rooms which appear to be from demarcation line deterioration that could be tracked into other areas.

OBSERVATION 3

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

Specifically,

Approximately 100 Events and 20 CAPA's from 2019-2021 are open past the completion due date deadline as defined in SOP PQ-5075.1 "Corrective and Preventative Action (CAPA) Management" Eff. 12/2018 and PQ-5245 "Event Investigations" Eff. 12/2018.

For example:

- 1) EV-0396 "Cefazolin hood ((b) (4)) pressure 0, power failure during (b) (4) " Date of Occurrence: 03/30/2020
- 2) EV-0961 "Personnel EM (forehead) > action limit w/ 35 CFUs; (b) (4) " Date of Occurrence: 04/05/2021
- 3) CA-0051 "Implement cleaning step (b) (4) for applicable batches." Date Issued: 09/23/2020
- 4) CA-0055 "Perform reinspection and single-unit packaging of manufactured batches (b) (4) until process change has been proven effective." Date Issued: 12/09/2020

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Quality fails to transfer all hand-written events from batch records to their internal event log. For example, batch record (b) (4) contains a hand-written note "Particle counter unable to obtain (b) (4) reading after (b) (4) runs. Re-cleaned (b) (4) and obtained (b) (4) reading. (b) (6) 06/29/21" This event was not transferred to their internal event log.

Quality failed to validate cleaning dwell times listed in SOP EV5010.2 Cleaning Program – 503B Cleanroom Effective 12/2019 for the detergent ((b) (4)) and disinfectant ((b) (4)) used in cleaning the ISO 5 hood. Additionally, the firm failed to provide justification for diluting their detergent (b) (4) with (b) (4) as shown in Batch record (b) (4) Lot# (b) (4) .

OBSERVATION 4

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

Specifically,

- Dynamic smoke studies performed in the ISO-5 hoods were not representative of conditions observed during production. The smoke study performed only included (b) (4) . On 7/12/21 during production of Lot (b) (4) up to 10 boxes of syringes, multiple packages of caps, two IV bags, and a balance were observed inside the ISO-5 processing area.
- After installation of a new (b) (4) Hood (b) (4) located in ISO 7 room (b) (4) on 4/10/21 a smoke study was not performed. This hood is currently in use for Cefazolin production and was used in producing multiple lots including Lot (b) (4) .

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."