DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
250 Marquette Ave, Ste. 600 Minneapolis, MN 55401 (612)334-4100 Fax:(612)334-4134	7/15/2025-7/25/2025* FEI NUMBER 3014483112

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

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

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 I OBSERVED:

OBSERVATION 1

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

Repeat Observation from FDA Inspections ending 09/19/2018, 08/02/2021, and 03/01/2024

Specifically,

1) On 7/15/2025, during production of Fentanyl Citrate 2500mcg CADD lot 20250715FEN-1, your production technicians performed the following poor aseptic techniques:
   a. Finished product vials of Fentanyl Citrate were uncapped within the ISO-7 area prior to filling vials into a pool bag.
   b. One technician in hood (b)(4) was seen throwing CADD cassette tubing caps from inside the ISO-5 hood to a trashcan located outside of the hood in the ISO-7 environment.

2) On 7/15/2025, during production of Oxytocin 30U/500mL bag lot 20250715OXY-2, your production technicians performed the following poor aseptic techniques:
   a. One technician in hood (b)(4) was seen handling product vials in a manner that blocked first pass air over vials that were being drawn up into a pool bag. The tops of vials were blocked by the technicians gloved hands.
   b. Finished product vials of Oxytocin were uncapped within the ISO-7 area prior to filling vials into a pool bag.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Logan T Williams, Investigator x Logan T Williams Investigator Signed By: 2002955055 Date Signed: 07-25-2025 08:06:44	7/25/2025

3) On 7/16/2025, during observation of visual inspection of Phenylephrine Hydrochloride 1000mcg/10mL lot 20250716PHE-2, one visual inspection technician was seen not inspecting product under both a (b) (4) background for the time required by procedure . In addition, their background and light were set up differently from the qualified set up.

4) Your firm has not demonstrated that media fill units are appropriately incubated to promote microbial growth. Your firm's growth promotion units for media fills are incubated under conditions that differ from the media fill units. Growth promotion units are incubated at your firm's contract laboratory at (b)(4) for (b)(4) days then (b)(4) for (b)(4) days. Media fill units are incubated at room temperature in the warehouse with limited controls over temperature and humidity. Media fill bag process lot (b)(4) BAG, was incubated at temperatures ranging from approximately (b)(4) Media fill CADD process lot (b)(4) CADD, was incubated at temperatures ranging from approximately (b)(4) The humidity limit for the warehouse is less than (b)(4)

OBSERVATION 2

The statistical quality control criteria fail to include appropriate rejection levels.

Specifically,

Your firm's 100% visual inspection reinspection AQL evaluation has an acceptance limit that is greater than the acceptance limits set for initial 100% visual inspection. The reinspection acceptance limit is not scientifically or statistically justified. Your firm released the following batches with critical defects identified during reinspection:

a)Fentanyl Citrate 2500mcg/50mL in sterile water lot 20240911FEN-1, expiry 3/10/2025, had an initial inspection of 11 critical particle defects found during 100% inspection. Your firm opened an investigation and reinspected the lot and found an additional 3 critical particle defects. This is above the limit of (b)(4) critical defects for reinspection for the batch size, per the production batch

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record. Your firm released this batch.

b)Cefazolin 3g/30mL lot 20240830CE2-1, expiry 11/28/2024, had an initial inspection of 4 critical particle defects found during 100% inspection. Your firm opened an investigation and reinspected the lot. Your firm found an additional 2 critical particle defects during 100% reinspection. This is equal to the limit of (b)(4) critical defects for reinspection for the batch size, per the production batch record. Your firm released this batch.

Neither investigation opened due to reinspection of the batch addressed why the critical defects were missed during initial 100% inspection. The firm did not evaluate the visual inspection process as a part of the investigations or the reason for missing critical defects on initial inspection.

OBSERVATION 3

Employees engaged in the manufacture and processing of a drug product lack the training required to perform their assigned functions.

Specifically,

1)Your firm's visual inspection (b) (4) used during qualification is not representative of the visual inspection process. During visual inspection of a production batch only one conta (b) (4) closure system type, size, and product are inspected at a time. Your firm's visual inspection (b) (4) contains units of various container closure systems, sizes, products, and defects.

2)Your firm does not have a library of defects from which on the job traini (b) (4) an be obtained. The only defects available for training are defects within the qualification (b) (4) All defects are not present in the visual inspection qualification (b) (4) Defects missing from (b)(4) include critical defects such as missing syringe cap, expired bags used for final product, and cracked syringe

barrels. In addition, particles contained in the qualification (b) (4) as critical defects are undefined as to composition, size, and origination (i.e. Extrinsic, Intrinsic, and Inherent). According to your firm's pharmacist, many of the particle defects are comprised of black pepper flakes and other particulate matter not found during routine production.

3)Your firm's qualification process does not assure that visual inspectors can identify defects based on the current process. For example, your qualification process does not simulate factors that can impact defect detection such as fatigue, adherence to inspection speed/procedure, and light intensity. In addition, your firm does not have limits for how long personnel can inspect without a break.

4)Your firm does not require vision acuity testing to be qualified to visually inspect.

OBSERVATION 4

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

Repeat observation from FDA inspections ending 08/02/2021 and 03/01/2024

Specifically,

Dynamic smoke studies were performed utilizing smoke from a combustible source, smoke matches. This smoke has not been evaluated by your firm for use in cleanroom hoods for factors such as sterility of smoke, particle generation, and cleanability of residues. In addition, smoke cannot be visualized in all smoke study videos due to blocked camera angles by personnel and manual application of smoke by personnel.

OBSERVATION 5

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Laboratory records do not include the initials or signature of a second person showing that the original records have been reviewed for accuracy and completeness.

Specifically,

Your firm does not perform contemporaneous two-person verification of environmental monitoring plates. A single laboratory technician reads environmental plate samples and records the results of the plate counts on a worksheet. There is no assurance that the operator has entered the data accurately.

OBSERVATION 6

The quality control unit lacks responsibility to approve all procedures or specifications impacting on the identity, strength, quality and purity of drug products.

Repeat observation from inspection ending 3/1/2024

Specifically,

Your firm failed to adequately assess the use of rapid sterility for your products including but not limited to reviewing the validation, reviewing the method for acceptability of use, and reviewing the equivalency testing to USP <71> for the release of all final products using rapid sterility.

***DATES OF INSPECTION**

7/15/2025(Tue), 7/16/2025(Wed), 7/17/2025(Thu), 7/18/2025(Fri), 7/21/2025(Mon), 7/22/2025(Tue), 7/23/2025(Wed), 7/24/2025(Thu), 7/25/2025(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Logan T Williams, Investigator	X Logan T Williams Investigator Signed By: 2002955055 Date Signed: 07-25-2025 08:08:44	7/25/2025

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."