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	8/4/2026-8/12/2026* FEI NUMBER 3014483112

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Craig Else, PharmD, MHSA, Chief Operating Officer

FIRM NAME	STREET ADDRESS
IntegraDose Compounding Services LLC	3650 Victoria St N Ste 900
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Shoreview, MN 55126-2906	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 WE OBSERVED:

OBSERVATION 1

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.

Specifically,

A. Your cleanroom certification conducted on June 29, 2026, and June 30, 2026, shows that HEPA Filter (b)(4) in Production Room (b)(4) (ISO 7) did not pass airflow and (b) (4) as the report states the result as N/A and notes "HEPA Filter 8 in need of motor replacement." Your firm produced (b) (4) batches of drug products in Production Room (b)(4) between June 30, 2026, and August 4, 2026, (b) (4) of which have been distributed. No investigation or CAPA has been opened to assess the impact of this specific HEPA Filter on your operations.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Sarah M Gauna, FDA Center Employee
Mary-Jeanet Mcgarry, FDA Center Employee

X Sarah M Gauna
FDA Center Employee
Signed By: 2004033743
Date Signed: 08-12-2026
11:32:40

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B. During the inspection walk through of your classified spaces on August 7, 2026, it was observed that HEPA filters in your ISO 7 production areas are equipped with indicator lights. Of the ten (10) HEPA filters observed, nine (9) displayed red indicator lights and one (1) displayed a green indicator light across the following areas: Production Room (b) (4) two (2) red indicator lights, Production Room (b) (4) three (3) red indicator lights and one (1) green indicator light, Production Room (b) (4) four (4) red indicator lights. Your firm explained that a green light indicates the HEPA filter is functioning and a red light indicates an issue with the filter. However, your firm was unable to identify the specific issue or issues indicated by the red-light status, had no documented procedure specifying the required response when a red light is displayed, and had no knowledge of when each affected HEPA filter began displaying the red light. Your firm did not restrict production activities in the affected areas or conduct an impact assessment on compounded drug products produced while these HEPA filters were displaying a red indicator light.

C. On August 5, 2026, while reviewing video recordings of the production of Hydromorphone HCL 20mg/100mL CADDS lot #20260720HYD-1, EXP November 17, 2026, completed on (b) (4) it was observed there were up to (b) (4) personnel present in Production room (b) (4) and (b) (4) operators in (b) (4) ISO 5 LAFH ((b) (4) during production operations. Your cleanroom certification report for June 29, 2026, and June 30, 2026, states that all (b) (4) of your classified spaces were certified under dynamic conditions with five personnel present. However, on August 10, 2026, a video of the firm's certification activities was reviewed. During this review, it was observed that only the certifier was present in each production room when certified. Additionally, your ISO 5 LAFHs (Production Room (b) (4) (b) (4) Production Room (b) (4) (b) (4) Production Room (b) (4) (b) (4) were all certified under dynamic conditions with one operator per the certification report.

D. On August 5, 2026, video recordings of the production of Hydromorphone HCL 20mg/100mL CADDS lot #20260720HYD-1, EXP November 17, 2026, completed (b) (4), were reviewed. During this video review several instances of poor aseptic practice were observed:

1. Operators were not consistently wiping components before introduction into the ISO 5 LAFH space from the ISO 7 Production room space.

Operators were moving quickly throughout the cleanroom space and within the ISO 5
2. LAFH. The tossing of components into the ISO 5 LAFH space was also observed.

This batch of Hydromorphone HCL 20mg/100mL CADDS lot #20260720HYD-1, completed on (b) (4), was released and distributed.

E. Continuing assessment for operator gowning qualification uses postproduction batch EM for assessment. Personnel sampling for gowning qualification should occur immediately after gowning and gloving. Using postproduction PM sampling does not show the operator's ability to gown properly. Additionally, twelve (12) of your (b) (4) operators did not perform initial hand hygiene and gowning qualifications at this location, they were carried over from IntegraDose's previous facility.

OBSERVATION 2

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

Specifically,

A. Your firm qualifies visual inspectors and AQL inspectors on (b) (4) basis. The following deficiencies in inspector qualification were identified during the inspection:

1. Following the start of operations at your new facility on February 2, 2026, your firm did not perform requalification of visual inspectors or AQL inspectors for the new facility. Instead, your firm continued to use qualifications performed at your previous facility. No assessment or justification for carrying over previous facility qualifications to the new facility was identified during the inspection. Visual inspection qualification is specific to the environment and equipment under which it is performed and qualifications conducted at a previous facility cannot be assumed to remain valid under the different conditions of a new facility.

2. In May 2026, your firm introduced (b) (4) new visual inspection booths in a new visual inspection room at your current facility. Your firm did not perform requalification of visual inspectors for these new booths prior to their use. As of the date of this inspection, inspectors have been performing visual inspection using these booths for approximately three months without qualification.

3. (b) (4) AQL inspectors have not performed any visual inspection or AQL inspection requalification since your firm began operations at the new facility in February 2026. These inspectors have performed AQL inspection on over (b) (4) batches between February 2026 and the date of this inspection, all of which have been distributed. Additionally, your AQL inspections are conducted by Production staff, your Quality Unit does not participate in AQL inspections.

B. Your firm's process media fill (MFP), qualifying your operators to perform aseptic operations, were not signed by your Quality Unit before your operators participated in production batches:

Process Media Fill	Date Completed	Date Signed by Quality Unit	Time Elapsed	Associated Event
(b) (4)	January 19, 2026	April 8, 2026	79 days	No Events
	January 26, 2026	April 22, 2026	86 days	No Events
	January 5, 2026	March 4, 2026	58 days	No Events
	January 7, 2026	March 11, 2026	63 days	No Events
	January 13, 2026	April 8, 2026	85 days	EV2319, EV2318

C. Your batch records do not document critical pieces of information related to the production and release of your drug products. Examples include but are not limited to the following:

1. Your firm uses a (b) (4) (Model (b) (4)) to (b) (4) incoming materials with a (b) (4) prior to introduction into the ISO 7 classified space. Per your firm, materials are (b) (4) and brought into the ISO 7 space. This (b) (4) process occurs in either the "Wipe (b) (4) or "Wipe (b) (4) room and is governed by Work Instruction WI-0040 wi for (b) (4) . However, the time at which (b) (4) begins, the (b) (4) dwell time for (b) (4) step, and the room in which (b) (4) occurs are not documented in the batch record.
2. Specific times and locations (Visual Inspection Room (b) (4)) that visual inspection took place, number of units visually inspected by each visual inspector, or when required breaks were taken by visual inspectors are not documented.
3. LUX lighting level of visual inspection areas is not documented prior to conducting visual inspection.

D. Your Quality Unit is not fulfilling its responsibility to ensure that your operations and processes are accurately described in current Standard Operating Procedures:

1. Your CADD (b) (4) process is governed by SOP-0055 *sop for* (b) (4) *and maintenance*, Effective date March 1, 2017. This SOP states "This machine is currently only approved for applying a tamper-evident (b) (4) on PCA vial products." According to your firm you have not used PCA vial products in approximately 7 years. Your firm is currently using the (b) (4) to create tamper evident (b) (4) on CADD products. No SOP governing the use of the (b) (4) for CADD tamper-evident (b) (4) was identified during the inspection.
2. The process of (b) (4) incoming material into the classified space is governed by WI-0040 wi for (b) (4) This work instruction provides locations and steps for (b) (4) material and components being brought into the ISO 8 classified space. The location names reflect rooms at your firm's previous facility. Your firm began operations at this new facility on February 2, 2026.
3. Your firm was observed using both a (b) (4) Microbial Sampler (Serial No.

(b) (4)) and a (b) (4) Sampler (Serial No. (b) (4)) for viable air sampling in your cleanrooms. However, your firm only has SOP-0064 (b) (4) *Microbiological (Viable) Air Sampler – Calibration, Operation, Use, and Maintenance, for viable air sampling equipment*. There is no SOP outlining the use of the (b) (4) Microbial Sampler.

OBSERVATION 3

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

Specifically,

Smoke studies conducted on December 31, 2025, did not adequately reflect observed production operations. On August 5, 2026, video recordings of the production of Hydromorphone HCL 20mg/100mL CADDS lot #20260720HYD-1, EXP November 17, 2026, completed on (b) (4) , were reviewed. The following discrepancies were observed in the smoke study videos:

1. The batch video, during production, showed (b) (4) operators performing individual tasks in each ISO 5 Laminar Airflow Hood (LAFH). The smoke studies only demonstrated one operator individually performing one task in each video.

2. The smoke study for the CADDs products shows the CADDs lined up with about 2 – 3 inches of space between the CADD and the back wall of the (b) (4) airflow LAFH. During the batch video the CADDs were observed to be placed directly in front of the back wall with no gap. The smoke study did not evaluate this product placement configuration and therefore does not demonstrate that unidirectional airflow adequately protects the critical compounding area under actual production conditions.
   Additionally, during production, CADDs were observed blocking first air for components placed behind the CADDs and the connectors of the CADDs were

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observed resting on the back wall of the LAFH where the HEPA filter is located.

This batch of Hydromorphone HCL 20mg/100mL CADDS lot #20260720HYD-1, completed on (b) (4), was released and distributed.

OBSERVATION 4

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

Specifically,

On August 5, 2026, video recordings of the production of Hydromorphone HCL 20mg/100mL CADDS lot #20260720HYD-1, EXP November 17, 2026, completed (b) (4), were reviewed. During this video review the following was observed:

1. Your production operators were observed placing the settle plates in the corners of the LAFHs before the start of the batch. Your SOP-0015 *Environmental Monitoring (EM) Program: 503B Cleanroom*, states placement should be "(b) (4) from the back/HEPA filter."
2. Your firm does not document the time post production EM samples are taken.

***DATES OF INSPECTION**

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Sarah M Gauna, FDA Center Employee Mary-Jeanet Mcgarry, FDA Center Employee	X Sarah M Gauna FDA Center Employee Signed By: 2004033743 Date Signed: 08-12-2026 11:32:40	8/12/2026

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8/04/2026(Tue), 8/05/2026(Wed), 8/06/2026(Thu), 8/07/2026(Fri), 8/10/2026(Mon), 8/11/2026(Tue), 8/12/2026(Wed)

X Mary-Jeanet Mcgarry
FDA Center Employee
Signed By: MARY-JEANETTE MCGARRY -S
Date Signed: 08-12-2026 11:33:12

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Sarah M Gauna, FDA Center Employee
Mary-Jeanet Mcgarry, FDA Center Employee

X Sarah M Gauna
FDA Center Employee
Signed By: 2004033743
Date Signed: 08-12-2026 11:32:40

DATE ISSUED
8/12/2026

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."