DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax:(615)366-7802 ORAPHARM2_RESPONSES@fda.hhs.gov	8/9/2021-8/19/2021* FEI NUMBER 3006372310

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Dean M. Lamb, Operations Manager	
FIRM NAME Intrathecal Compounding Specialists, LLC	STREET ADDRESS 206a Jacobs Run
CITY, STATE, ZIP CODE, COUNTRY Scott, LA 70583-8907	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drug Products

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

You did not make adequate product evaluation and take remedial action where actionable microbial contamination was found to be present in the ISO 5 classified aseptic processing area during aseptic production.

Specifically,

a) You had four fingertip environmental monitoring results in the ISO 5 environment where you did not identify the microorganism and continued to produce and distribute sterile drug products without a complete investigation and corrective action taken.

Employee	Date	CFUs	L/R Hand	Lots Compounded
(b) (6)	9/16/2020	2	L	(b) (4)
	12/9/2020	1	R	
	3/18/2021	1	L	
	6/14/2021	2	R	

b) Additionally, you lack adequate routine environmental monitoring. You only take surface samples (b) (4) and rotate (b) (4) fingertip samples between (b) (4) employees who compound.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Claire M Minden, Investigator		DATE ISSUED 8/19/2021
		X Claire M Minden Investigator Signed By: Claire M. Minden -S Date Signed: 08-19-2021 08:29:52	

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OBSERVATION 2

Disinfecting agents and cleaning pads and cleaning wipes used in the ISO 5 classified aseptic processing areas were not sterile.

Specifically,

a) You use (b) (4) and (b) (4) which are not sterile for daily cleaning of LFHs (ISO 5) and the clean room suite.
b) Additionally, the (b) (4) wipes are opened and stored outside the LFHs for multiple days exposing the individual wipes to lesser quality air prior to use inside the LFHs (ISO 5) without any decontamination upon introduction into the LFHs.

OBSERVATION 3

Disinfectant contact time (also known as "dwell time") and coverage of the item being disinfected were insufficient to achieve adequate levels of disinfection.

Specifically, during the daily cleaning of the clean room I observed on August 10, 2021, each of your disinfectants ((b) (4) wipes and spray and (b) (4) spray) used within the ISO 5 and ISO 7 environments had a less than (b) (4) wet contact time, despite the supplier's established (b) (4) minimum contact time needed for the disinfectant to achieve the necessary log reduction of microorganisms.

***DATES OF INSPECTION**

8/09/2021(Mon), 8/10/2021(Tue), 8/11/2021(Wed), 8/19/2021(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Claire M Minden, Investigator X Claire M Minden Investigator Signed By: Claire M. Minden -S Date Signed: 08-19-2021 08:29:52	8/19/2021

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."