

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 2/10/2020-2/14/2020, 2/20/2020
	FEI NUMBER 3013556857

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Nasim P Barrack, Pharmacist in Charge and Partial Owner

FIRM NAME Innovative Intrathecal Solutions, Inc. dba**	STREET ADDRESS 41538 Eastman Dr Ste A
---	--

CITY, STATE AND ZIP CODE Murrieta, CA 92562-8007	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile and Non-sterile Drugs
---	--

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) (WE) OBSERVED:

OBSERVATION 1

The ISO 5 classified aseptic processing areas had difficult to clean and visibly dirty equipment or surface.

Specifically,

From 02/10-14/2020, within the ISO 7 classified clean room, the (b)(4) ISO 5 classified laminar airflow hoods used for sterile drug processing contained visible discoloration and yellow stains on the glass, yellow-brown stains at the junction of the glass to the work surface, a solid brown stain at the HEPA filter in hood (b)(4) spotty brown stains on the HEPA filter in hood (b)(4) and brown spotty stains at the grating in front of the HEPA filter in hood (b)(4). The glass to work surface junctions contain difficult to clean gaps. In addition, there are porous spaces on the surfaces beneath the ISO 5 hoods, dark brown stained shelving adjacent to the hoods, peeling paint in the drawers and brown residue on the drawer hinges adjacent to the hoods, and cardboard material in the shelves and cabinets within the cleanroom. (b)(4) of Atropine eye drops lot 02122020@8 occurred on 02/12/2020 in ISO 5 hood (b)(4) in the presence of these visibly dirty surfaces and equipment. Drugs produced in these hoods in the cleanroom include but are not limited to:


- Morphine Sol 25mg/mL Inj Lot 02112020@51
 - Hydromor 25mg + Bar 2mg/mL Inj Lot 02112020@61
 - Morphine Sol 25mg/mL Inj Lot 02122020@18
 - Baclofen 200mg/mL Inj Lot 02132020@3
- KCP
02/10/2020

OBSERVATION 2

You had inadequate HEPA filter coverage and airflow over the area to which sterile product was exposed.

Specifically,

On 11/25/2019, during the ISO Classified Room and Laminar Airflow Hood recertifications, ISO 5 Hood Serial

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Rumany Penn, Investigator	DATE ISSUED 02/20/2020
-----------------------------------	--	---	---------------------------

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 2/10/2020-2/14/2020, 2/20/2020
	FEI NUMBER 3013556857

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Nasim P Barrack, Pharmacist in Charge and Partial Owner

FIRM NAME Innovative Intrathecal Solutions, Inc. dba**	STREET ADDRESS 41538 Eastman Dr Ste A
CITY, STATE AND ZIP CODE Murrieta, CA 92562-8007	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile and Non-sterile Drugs

Number (b) (4) had a 0.10% leak result requiring a 1/2" x 4" patch and ISO 5 Hood Serial Number (b) (4) had two leaks greater than 0.04% leak results requiring two patches sized 1/2" x 2" and 1" x 2". Drugs produced within these ISO 5 hoods prior to the discovery of the leak and after the previous passing leak test on July 9, 2019, include but are not limited to:

- Hydromorphone 1 mg + Clonidine 100 mcg / mL intrathecal Injection lot 11222019@41
- Hydromorphone 20 mg + Bup 800mcg / mL intrathecal Injection lot 11222019@40
- Morphine Sul 3 mg/mL Intrathecal intrathecal Injection lot 11222019@37
- Edetate disodium Ophthalmic 3% drops lot 11222019@27
- Fentanyl 4mg + Bup 10 mg /mL intrathecal Injection lot 11222019@17
- Baclofen 250 mcg/mL intrathecal Injection lot 11222019@21
- Methylprednisolone 80 mg/mL injection lot 11202019@60
- Sufentanil 5000 mcg + Bup 10 mg + Clonidine 500 mcg / mL injection lot 11202019@27
- Fentanyl Citrate 35 mg/mL intrathecal injection lot 11202019@32
- Droperidol 2000 mcg/mL injection lot 11192019@62


OBSERVATION 3

Your firm failed to conduct adequate cleaning and disinfection in aseptic processing areas.

Specifically,

1. On 02/10/2020, the (b) (4) ISO 5 laminar air flow hoods were in the off position, and stated to be off throughout the weekend. No additional cleaning, sanitation, or environmental sampling was conducted following the shutdown of the ISO 5 hoods. Drugs produced after the shutdown of the hoods include but are not limited to:

- Morphine Sul 25 mg/mL Inj Lot 02112020@51
 - Hydromorphone 25 mg + Bup 2 mg/mL Inj lot 02112020@61
 - Baclofen 2000 mcg/mL Inj lot 02132020@3
 - Baclofen 4000 mcg/mL PFS sol inj lot 02102020@26
- RCP*
02/20/2020

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Rumany Penn, Investigator	DATE ISSUED 02/20/2020
--------------------------	--	---	---------------------------

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 2/10/2020-2/14/2020, 2/20/2020
	FEI NUMBER 3013556857

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Nasim P Barrack, Pharmacist in Charge and Partial Owner

FIRM NAME Innovative Intrathecal Solutions, Inc. dba**	STREET ADDRESS 41538 Eastman Dr Ste A
CITY, STATE AND ZIP CODE Murrieta, CA 92562-8007	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile and Non-sterile Drugs

OBSERVATION 4
 Materials or supplies were not disinfected prior to entering the aseptic processing areas.

Specifically,
 During the (b) (4) of Atropine eye drops lot 02122020@8 in ISO 5 Laminar Airflow Hood (b) (4) on 02/12/2020, the syringe tip caps, needle packages, and dropper bottle packaging were not disinfected prior to entering into the ISO 5 classified laminar air flow hood from the ISO 7 classified clean room shelving and cabinets. Original cardboard outer packaging is also stored in the ISO 7 areas.

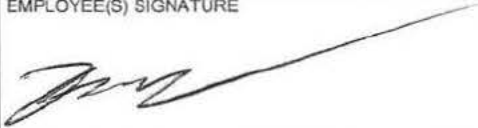
OBSERVATION 5
 Personnel engaged in aseptic processing were observed with exposed hair.

Specifically,
 During the (b) (4) of atropine eye drops lot 02122020@8 in ISO 5 Laminar Airflow Hood (b) (4) on 02/12/2020, the pharmacist was observed with exposed hair while working in the ISO 5 laminar airflow hood stationed within the ISO 7 cleanroom.

OBSERVATION 6
 The (b) (4) intended to render final product sterile was not pharmaceutical grade.

Specifically,
 The pharmacist stated the (b) (4) (product code (b) (4)) is used to produce oil based sterile drug products such as Testosterone Cyp IM injection and Hydroxyprogesterone IM injection. The (b) (4) states its use as "(b) (4)" It does not indicate that it is pharmaceutical grade. Drugs produced using this (b) (4) include but are not limited to:

- Hydroxyprogesterone Caproate 350 mg/mL Injection lot 01162020@56
- Testosterone Cypionate 200 MS prescription (b) (6)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Rumany Penn, Investigator	DATE ISSUED 02/20/2020
--------------------------	--	---	---------------------------

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 2/10/2020-2/14/2020, 2/20/2020
	FEI NUMBER 3013556857

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Nasim P Barrack, Pharmacist in Charge and Partial Owner

FIRM NAME Innovative Intrathecal Solutions, Inc. dba**	STREET ADDRESS 41538 Eastman Dr Ste A
CITY, STATE AND ZIP CODE Murrieta, CA 92562-8007	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile and Non-sterile Drugs

OBSERVATION 7

You used a non-pharmaceutical grade component in the formulation of a drug product.

Specifically,

1. Food grade (b) (4) was used for the production of Progesterone Vaginal Suppository Capsules lot 01102020@5
2. Food grade (b) (4) was used for Eugenol topical dental cream lot 01232020@28.

OBSERVATION 8

Environmental monitoring was inadequately performed in your aseptic processing areas.

Specifically,


The pharmacist stated that sampling for microbial contamination analysis is collected on personnel fingertips and ISO 5 surface areas after sanitation and cleaning of the areas with sterile (b) (4) spray on sterile wipes. This method does not allow for adequate product evaluation to determine if microbial contamination was present during aseptic production.

OBSERVATION 9

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

Specifically,

Media fills conducted on 01/08/2019, 07/08/2019, and 11/25/2019 are performed using operations consisting of drawing up syringes to produce (b) (4) mL vials via (b) (4). Your worst-case activity and most challenging operation includes (b) (4) into batch sizes as large as (b) (4) units of (b) (4) mL vial stock solutions which are then further processed into intrathecal syringes. In addition, media fills do not reflect the normal pharmacist operations observed in the ISO 5 aseptic processing hoods in which the pharmacists move themselves and materials over 6 times between the ISO 5 aseptic processing hoods and the ISO 7 environment.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Rumany Penn, Investigator	DATE ISSUED 02/20/2020
-----------------------------------	--	---	---------------------------

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 2/10/2020-2/14/2020, 2/20/2020
	FEI NUMBER 3013556857

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Nasim P Barrack, Pharmacist in Charge and Partial Owner

FIRM NAME Innovative Intrathecal Solutions, Inc. dba**	STREET ADDRESS 41538 Eastman Dr Ste A
CITY, STATE AND ZIP CODE Murrieta, CA 92562-8007	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile and Non-sterile Drugs

OBSERVATION 10

You produced hazardous drugs without providing adequate cleaning of work surfaces and cleaning of utensils to prevent cross-contamination.

Specifically,

The (b) (4), (b) (4) brand (b) (4) are used interchangeably for production of non-sterile hazardous drugs and non-hazardous drugs. The (b) (4) are not identified and are moved between the hazardous negative pressure room, the buffer room, and the unclassified non-sterile production hallway (b) (4) are cleaned with (b) (4) solution with no assurance that the cleaning solution acts as a deactivating agent.

The pharmacist stated the following non-sterile drugs were produced using the (b) (4)


- Progesterone 160 mg/gm phytobase, (hazardous) lot 02032020@68 on 02/03/2020 using an unidentified (b) (4) (b) (4)

- Nitroglycerin 0.15% Ointment, (non-hazardous) lot 02062020@27 on 02/06/2020 using an unidentified (b) (4) (b) (4)

***DATES OF INSPECTION**

2/10/2020(Mon), 2/11/2020(Tue), 2/12/2020(Wed), 2/13/2020(Thu), 2/14/2020(Fri), 2/20/2020(Thu)

**dba: Innovative Compounding Pharmacy

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Rumany Penn, Investigator	DATE ISSUED 02/20/2020
--------------------------	--	---	---------------------------