DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314 ORAPHARM2_RESPONSES@fda.hhs.gov	5/11/2021-5/27/2021* FEI NUMBER 3012907473

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Kevin P. Hogan, President/Owner	
FIRM NAME Innoveix Pharmaceuticals Inc	STREET ADDRESS 3790 Arapaho Rd
CITY, STATE, ZIP CODE, COUNTRY Addison, TX 75001-4311	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non Sterile Human 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

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

Specifically,

Your firm's Pharmacist in Charge (PIC) uses a non-pharmaceutical grade (b) (4) unit to (b) (4) injectable drug preparations that are (b) (4) prior to administering to patients subcutaneously or intramuscularly.

On 05/12/2021, I observed the PIC use a sterile non-pharmaceutical grade (b) (4) unit to (b) (4) Sermorelin/Ipamorelin 3mg Injection Solution, Lot SIP225. In addition, post use (b) (4) testing was not performed and your firm has not conducted (b) (4) tests since January 23, 2021.

OBSERVATION 2

Personnel conducted aseptic manipulations in an area that blocked movement of first pass air around an open unit, either before or after it was filled with sterile product.

Specifically,

On 5/12/21, your firm's Pharmacist in Charge (PIC) was aseptically filling glass vials with Sermorelin/Ipamorelin 3mg Injection Solution, Lot SIP225 in the ISO5 biosafety cabinet. I observed the PIC aseptically fill the first row of glass vials, aseptically (b) (4) the vials and remove the (b) (4) vials to a

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	Patty P Kaewussdangkul, Investigator	X Patty P Kaewussdangkul Investigator Signed By: Patty P. Kaewussdangkul -S Date Signed: 05-27-2021 10:52:01	5/27/2021

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different tray before filling the next row. However, after approximately 20 minutes, I observed the PIC block the unidirectional flow with his hand and wrist to the first row of open glass vials containing sterile product while aseptically filling the second row.

OBSERVATION 3

(b) (4) is not sterilized by routine sterilization cycles and cleaning process of the (b) (4) is inadequate.

Specifically,

Your firm's Pharmacist in Charge (PIC) does not know whether or not the (b) (4) used to (b) (4) sterile injectable drug products has a sterilization, sanitization and/or clean in place cycle. Furthermore, your PIC stated that he uses sterile (b) (4) wipes to clean the interior of the (b) (4) which alone is not adequate.

OBSERVATION 4

Failure to conduct media fills that closely simulates aseptic production operations under the worst case, most challenging and stressful conditions.

Specifically,

Your firm's Pharmacist in Charge (PIC) routinely compounds up to (b) (4) vials of sterile injectable drug products per batch. According to your PIC, firm's smallest batch size of sterile injectable drug products is (b) (4) vials. However, your media fill consists of a total of (b) (4) test vials. Furthermore, your PIC does not include the (b) (4) step in your media fill process.

OBSERVATION 5

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Glass vials intended to be sterile and (b) (4) used for finished sterile injectable drug products was inadequately wrapped with foil and was observed to be exposed to lower than ISO5 quality air.

Specifically,

On 5/11/2021, I observed your firm's Pharmacist in Charge (PIC) remove two trays containing glass vials that were sterilized and (b) (4) in the (b) (4) which is located in an unclassified storage room. They were loosely wrapped with tin foil that the sides of the stainless steel trays and glass vials were visible. Loosely wrapped trays do not ensure that the vials are protected from less than ISO5 quality air. Furthermore, the loosely wrapped trays were placed in the (b) (4) without disinfecting.

OBSERVATION 6

Method suitability has not been conducted on your sterile drug products that are sent for sterility testing.

Specifically,

Your Pharmacist in Charge (PIC) stated that (b) (4) vials of each batch of sterile (b) (4) injectable drug products is sent to a third-party contract laboratory for sterility testing using the (b) (4) Test method. However, you have not conducted method suitability to ensure that your sterile (b) (4) injectable drug products are not inhibitory or interfere with sterility test method used.

OBSERVATION 7

You firm uses a non-pharmaceutical grade detergent to clean and sanitize glassware used in the production of your compounded sterile (b) (4) injectable drug products.

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Your firm uses a household detergent, (b) (4) to clean and sanitize reusable glass beakers and glass rods that are routinely used in the production of your compounded sterile (b) (4) injectable drug products. You have not established that your cleaning process is adequate to remove detergent residues from your glassware.

OBSERVATION 8

The cycle parameters (temperature, pressure and time) used for (b) (4) of product intended to be sterile were not lethal to heat-resistant microorganisms.

**Repeat Observation **

Specifically,

1. Your firm uses the (b) (4) to sterilize and (b) (4) glass vials, glass beakers and glass rods used in the preparation of your firm's sterile injectable drug products. However, you do not use biological indicators or endotoxin indicators to ensure and verify that the temperature and time cycle used to sterilize and (b) (4) glassware is adequate.

2. Your firm uses (b) (4) to sterilize rubber stoppers, caps, goggles, scissors and crimpers used in the preparation of your firm's sterile injectable drug products. However, you do not use a biological indicator to verify and ensure that the temperature, time and pressure cycle used to sterilize equipment is adequate.

OBSERVATION 9

Disinfecting agents used in the ISO 5 classified aseptic processing areas were not sterile.

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During the walk through of your firm's facility conducted on 5/11/21, your Pharmacist in Charge (PIC) explained that the (b) (4) located in a wall dispenser next to the (b) (4) was used as a hands free way to disinfect hands during the aseptic production process of the firm's sterile injectable drug products. He explained that he takes the sterile (b) (4) from its original sterile container that is commercially purchased and places it in the reusable bottle which renders the (b) (4) no longer sterile. The PIC ceased using this the (b) (4) on 5/11/21 however, since January 1, 2020 approximately (b) (4) batches of Sermorelin/Ipamorelin 3mg Injection were aseptically processed using the non-sterile (b) (4) to disinfect hands.

***DATES OF INSPECTION**

5/11/2021(Tue), 5/12/2021(Wed), 5/13/2021(Thu), 5/14/2021(Fri), 5/17/2021(Mon), 5/18/2021(Tue), 5/27/2021(Thu)

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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."