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	1/27/2025-2/7/2025* FEI NUMBER 3016710945

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Aaron M. Schneider, Chief of Pharmacy/ Co-Owner

FIRM NAME	STREET ADDRESS
Revive Rx LLC dba Revive Rx Pharmacy	3831 Golf Dr Ste A
CITY, STATE, ZIP CODE, COUNTRY Houston, TX 77018-5218	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-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

Sterile drugs and Materials were exposed to lower than ISO 5 quality air.

Specifically,

A. Your firm's drug product, Trimix Gel (300 mcg / 100 mcg / 1000 mcg per ml), is prepared with nonsterile (b) (4) that is (b) (4) to be sterilized uncapped (b) (4) staged in an unclassified area. After the sterilization cycle, the opened and uncapped syringe is then capped using a 'sterile' cap before it is transferred into ISO 8/7 areas and ultimately, into a ISO 5 BSC for further processing. On 12/05/2024, your firm prepared (b) (4) syringes units of Trimix Gel (300 mcg/ 100 mcg/ 1000 mcg per ml) for Intraurethral Insertion, Lot 10099621, BUD:03/05/2025, with an uncapped (b) (4) that was processed using (b) (4) in an unclassified area. There is no assurance that the unclassified area where the non-sterile (b) (4) is sterilized and use of a 'sterile cap' are not rendered unsterile when exposed in an uncontrolled environment that is less than ISO 5 critical air.

B. Your firm transfers (b) (4) vials filled with drug product from an ISO 5 BSC to a (b) (4) located within an ISO 7 area, thereby exposing those drug products intended to be sterile to worse than ISO 5 qualified air. On 11/24/2024, your firm transferred (b) (4) units of drug product intended to be sterile from the ISO 5 BSC, hood (b) (4) through the ISO 7 negative cleanroom area to use the (b) (4) Trimix (150mg/ 5mg/ 50 mcg per vial) for Injection with Trehalose, Lot 9924515, BUD: 05/06/2025.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jazmine N Brown, Investigator	X Jazmine N Brown Investigator Signed By: JAZMINE N. BROWN -S Date Signed: 02-07-2025 14:05:52	2/7/2025

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	1/27/2025-2/7/2025* FEI NUMBER 3016710945

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Aaron M. Schneider, Chief of Pharmacy/ Co-Owner

FIRM NAME	STREET ADDRESS
Revive Rx LLC dba Revive Rx Pharmacy	3831 Golf Dr Ste A
CITY, STATE, ZIP CODE, COUNTRY Houston, TX 77018-5218	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drug Products

OBSERVATION 2

Microbial contamination was present in the ISO 5 area and areas adjacent to production areas.

Specifically,

A. Your firm fails to add additional routine environmental monitoring to the ISO 5 and ISO 7 critical areas to ensure that the processing conditions are free of mold, yeast, and other spore forming microorganisms found in your ISO 7 cleanroom areas and during routine personnel gowning qualifications.
   i. On 01/24/2024, a recovery of Too Numerous To Count (TNTC) CFU of a gram-positive, spore forming bacteria, *Paenibacillus glucanolyticus,* was recovered in the ISO 7 prep cleanroom used to prepare and mix solutions;
   ii. On 11/23/2023, a 3CFU recovery of mold, *Penicillium sumatrense,* was recovered in the ISO 7 preparation (b) (4) hood used to prepare and mix solutions;
   iii. On 08/01/2023, there were three separate recoveries inside the ISO 7 negative pressure clean room used in the processing of drug products intended to be sterile, 1 CFU of a unknown species of *Streptococcus*, 2CFU of mold microorganism, *Penicillium ciltrinum*, and 3 CFU of another mold species, *Penicillium sumatrense*.
   iv. On 09/03/2024, a passing gowning competency check for aseptic operator (b) (7)(C). was sampled to have 1 CFU of Aspergillus and 2 CFUs of a gram-positive cocci, both recovered on their forehead.

B. While your firm has defined an action limit of (b) (4) CFU it was changed in December 2024 to a specification of (b) (4) CFU within the ISO 5 critical area. Your firm failed to address these excursions and released the following batches for distribution:
   i. On 12/4/2024, your firm had 1 cfu recovery identified as *Staphylococcus* species in hood (b) (4) during the production of Tirzepatide Lot: 10090131, BUD: 06/02/2025.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	1/27/2025-2/7/2025* FEI NUMBER 3016710945

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Aaron M. Schneider, Chief of Pharmacy/ Co-Owner	
FIRM NAME Revive Rx LLC dba Revive Rx Pharmacy	STREET ADDRESS 3831 Golf Dr Ste A
CITY, STATE, ZIP CODE, COUNTRY Houston, TX 77018-5218	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drug Products

ii. On 10/2/2024, your firm had 1 CFU recovery identified as *Actinomyces* species in hood [(b)(4)] during the production of Testosterone cypionate, Lot: 9685326 BUD: 03/25/2025.

iii. On 06/24/2024, your firm had two recoveries in hood 3 during the production of HCG 12,000 unit vials Lot 9089665 BUD: 12/21/2024. The initial sample had 1 CFU identified as *Staphylococcus epidemidis* and 2 CFU identified as *Staphylococcus hominis*.

C. On 08/1/2023, your firm had ten separate recoveries identified as either *Neissaria, Penicillium citrinum*, *Cladosporium, Streptococcus* or *Micrococcus* species within your ISO 7 hazardous negative cleanroom, which was not addressed through an investigation, additional sampling, or robust cleaning. Furthermore, on 08/01/2023, two recoveries out of the ten documented having 2 CFUs and 1CFU (Action Limit [(b)(4)] CFUs) identified as *Micrococcus luteus* and one recovery of 1CFU identified as *Micrococcus* species found in BSC hood# [(b)(4)] which was used to produce sterile drug product.

D. On 08/06/2024, your aseptic technician performed a gloved fingertip sample during a media fill performance while inside of BSC hood [(b)(4)] and a recovery of 1 CFU (Action Limit [(b)(4)] CFU) of *Bacillus* species was found. Both media fill and environmental monitoring performed in concert are documented as successful without any evaluation for the microorganism recovery.

OBSERVATION 3

Lack of and Inadequate routine environmental monitoring in the ISO 5 area and classified areas.

Specifically, your firm does not perform an environmental monitoring surface sample when performing aseptic processing directly in within 6 inches of the work area that the process is being performed. On 01/27/2025, the firm 's quality technician was observed to take a sample of the work bench

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jazmine N Brown, Investigator X Jazmine N Brown Investigator Signed By: JAZMINE N. BROWN -S Date Signed: 02-07-2025 14:05:52	2/7/2025

approximately a foot away from the direct area drug product purported to be sterile was filled in. Furthermore, when placing the media plate inside the ISO 5 BSC a copious amount of sterile (b) (4) was directly sprayed on the closed media plate which was then placed directly on the work surface which was directly sampled once opened and applied to the work bench area during the production of Semaglutide 5mg/ml 2cc, Lot 10453555 BUD 4/27/2025.

OBSERVATION 4

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

Specifically, your firm's media fill program is deficient in that your media fills are not representative of the batch size, container type, and equipment used for all drug products produced intending to be sterile.

A. Your firm does not have a media fill for syringe drug products produced. For example, your firm prepares (b) (4) syringes at (b) (4) / syringe for Trimix Gel (300 mcg / 100 mcg / 1000 mcg per ml) for Intraurethral Insertion without having conducted the appropriate media fill to demonstrate and assess aseptic processing when filling a syringe product inside of the ISO 5 environment.

B. Your firm does not include interventions such as loading and unloading the (b) (4) in your media fill program. The following products are (b) (4) :
Bimix (150 mg / 5 mg) per Vial for Injection
FSH 1500 IU Vial for Injection
Hexarelin 6 mg per Vial for Injection
Human Chorionic Gonadotropin (hCG) 6,000 IU Vial For Injection
Human Chorionic Gonadotropin (hCG) 12,000 IU Vial For Injection
Human Chorionic Gonadotropin (hCG) 50,000 IU Vial For Injection
NAD+ 1000 mg per Vial for Injection

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	1/27/2025-2/7/2025*
	FEI NUMBER 3016710945

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Aaron M. Schneider, Chief of Pharmacy/ Co-Owner	
FIRM NAME Revive Rx LLC dba Revive Rx Pharmacy	STREET ADDRESS 3831 Golf Dr Ste A
CITY, STATE, ZIP CODE, COUNTRY Houston, TX 77018-5218	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drug Products

Quadmix (150 mg / 10 mg / 100 mcg / 1000 mcg) per Vial for Injection
Sermorelin 15 mg per Vial for Injection
SS-31 300 mg per Vial For Injection
Tesamorelin 12 mg per Vial for Injection
Trimix (150 mg / 5 mg / 50 mcg) per Vial for Injection
Trimix XL (150 mg / 10 mg / 100 mcg) per Vial for Injection
Trimix 60 (150 mg / 30 mg / 300 mcg) per Vial for Injection
Gonadorelin 2 mg per vial for Injection

OBSERVATION 5

Smoke studies were not performed under dynamic conditions.

Specifically, your smoke studies conducted August 22, 2024, during the cleanroom recertification, are inadequate. For example, your firm's smoke studies do not consist of dynamic behaviors performed to assess complex interventions within the ISO 5 biosafety cabinet hoods class (b) (4).

This is a repeat OBSERVATION.

OBSERVATION 6

Failure to appropriately and regularly clean and disinfect or sterilize equipment located in the ISO 5 area.

Specifically, your firm has not established a process for (b) (4) cleaning of the metal diffuser covering the HEPA filters within the (b) (4) biosafety cabinet (BSC) class (b) (4) used to produce drug products purported to be sterile. Your firm produces approximately (b) (4) lots (b) (4) across the (b) (4) BSCs located in your clean room suites. For example, on 01/27/2025, your operator made two different drug

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jazmine N Brown, Investigator	X Jazmine N Brown Investigator Signed By: JAZMINE N. BROWN -S Date Signed: 02-07-2025 14:05:52	2/7/2025

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	1/27/2025-2/7/2025*
	FEI NUMBER 3016710945

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Aaron M. Schneider, Chief of Pharmacy/ Co-Owner

FIRM NAME	STREET ADDRESS
Revive Rx LLC dba Revive Rx Pharmacy	3831 Golf Dr Ste A
CITY, STATE, ZIP CODE, COUNTRY Houston, TX 77018-5218	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drug Products

products in the (b) (4) ISO 5 BSC hood (b) (4) with only a sanitization to the back, top bar, side walls, and work surface area of the BSC, missing the front metal diffuser before producing the second drug product made in the same (b) (4) BSC. Your firm failed to adequately clean the BSC to prevent potential cross contamination. Two drugs were observed were Semaglutide 5mg/ml 2cc, Lot 10453555 BUD 4/27/2025, and Semorelin 15mg , Lot 10453561 BUD 7/26/2025.

OBSERVATION 7

Use of lyophilizers that are not sterilized by routine sterilization cycles and protected from contamination by sterilizing filters on vacuum break air lines/vents.

Specifically, your firm does not use the sterilization cycle on the four (b) (4) units within your clean room areas to protect them from contamination. Furthermore, the (b) (4) units are not monitored using meaningful environmental monitoring data to include surface, viable active air, or non-viable air samples inside the (b) (4) units.

***DATES OF INSPECTION**

1/27/2025(Mon), 1/28/2025(Tue), 1/29/2025(Wed), 1/30/2025(Thu), 1/31/2025(Fri), 2/03/2025(Mon), 2/04/2025(Tue), 2/05/2025(Wed), 2/07/2025(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jazmine N Brown, Investigator	X Jazmine N Brown Investigator Signed By: JAZMINE N. BROWN -S Date Signed: 02-07-2025 14:05:52	2/7/2025

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."