

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHONE NUMBER 1201 Main Street, Suite 7200 Dallas, TX 75202 (214) 253-5200 Fax: (214) 253-5314		DATE(S) OF INSPECTION 8/20/2026-8/28/2026* FEI NUMBER 3045022201			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Stuart E. Tolman, R.Ph., Pharmacist-in-Charge					
FIRM NAME Houston Rx LLC		STREET ADDRESS 15340 Vantage Pkwy E Ste 220			
CITY, STATE, ZIP CODE, COUNTRY Houston, TX 77032-1901		TYPE ESTABLISHMENT INSPECTED Producer of 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 WE OBSERVED: OBSERVATION 1 Personnel performed aseptic manipulations with exposed hair or skin. Specifically, on August 24, 2026, while filling/stoppering lot #SMN-082426-5/2-5 of Semaglutide/Niacinamide 5mg/2mg/1mL, we observed one of the operators working in the ISO 5 laminar flow hood with exposed skin on her forehead. The operator was observed entering the ISO 5 LFH, leaning over the bag of sterilized stoppers within the ISO 5 LFH, and placing stoppers on the recently filled vials.					
OBSERVATION 2 A pattern of frequent or acute pressure reversals was observed from areas of less clean air to areas of higher air cleanliness. Specifically, from July 10, 2026 to August 21, 2026, your system for measuring pressure differential in the cleanrooms indicates negative pressure between the ISO 7 Buffer Room where the ISO 5 Laminar Flow Hoods are located and the ISO 8 Ante Room. The specification is (b) (4) w.c. and every data point documented in this time period was below 0.00" w.c. Your firm has made at least (b) (4) lots of various drug products in this time period. All have been released.					
SEE REVERSE OF THIS PAGE		<table border="0" style="width: 100%;"> <tr> <td style="width: 60%;"> EMPLOYEE(S) SIGNATURE Margaret M Annes, CSO Megan T Ziegler, Investigator </td> <td style="width: 40%; text-align: center; vertical-align: bottom;"> Margaret M Annes CSO Signed By: MARGARET M. ANNES-S Date Signed: 08-28-2026 14:17:31 X </td> </tr> </table>		EMPLOYEE(S) SIGNATURE Margaret M Annes, CSO Megan T Ziegler, Investigator	Margaret M Annes CSO Signed By: MARGARET M. ANNES-S Date Signed: 08-28-2026 14:17:31 X
EMPLOYEE(S) SIGNATURE Margaret M Annes, CSO Megan T Ziegler, Investigator	Margaret M Annes CSO Signed By: MARGARET M. ANNES-S Date Signed: 08-28-2026 14:17:31 X				
DATE ISSUED 8/28/2026					

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

DISTRICT ADDRESS AND PHONE NUMBER 1201 Main Street, Suite 7200 Dallas, TX 75202 (214) 253-5200 Fax: (214) 253-5314	DATE(S) OF INSPECTION 8/20/2026-8/28/2026* FEI NUMBER 3045022201
---	---

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Stuart E. Tolman, R.Ph., Pharmacist-in-Charge

FIRM NAME Houston Rx LLC	STREET ADDRESS 15340 Vantage Pkwy E Ste 220
CITY, STATE, ZIP CODE, COUNTRY Houston, TX 77032-1901	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drugs

OBSERVATION 3

Inadequate (b) (4) testing on (b) (4) used to sterilize drug products.

Specifically, your firm is not conducting (b) (4) testing (b) (4) appropriately as recommended by the (b) (4) manufacturer. Your firm has not identified an appropriate (b) (4) agent and you do not (b) (4) the (b) (4) before testing. (b) (4), you attach (b) (4) to one end of the (b) (4) and attach the other end of the (b) (4) to a (b) (4). You then (b) (4) the (b) (4) in (b) (4) (b) (4) from the (b) (4) through the (b) (4) and look for (b) (4) in the (b) (4). On August 24, 2026, we watched (b) (4) testing of the (b) (4) used in the preparation of lot #SMN-082426-5/2-5 of Semaglutide/Niacinamide 5mg/2mg/1mL performed in this manner.

OBSERVATION 4

Personnel were observed manually contacting the inner surface of a sterile container or closure and manually touching a sterile product contact surface.

Specifically, on August 24, 2026, we watched the filling and stoppering of lot #SMN-082426-5/2-5 of Semaglutide/Niacinamide 5mg/2mg/1mL. Your practice is to place the sterile stoppers onto the filled vials using (b) (4) and then pressing down on the stoppers with your (b) (4) to push the stopper into the vial.

OBSERVATION 5

Microbial contamination was present in the ISO 5 area.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Margaret M Annes, CSO Megan T Ziegler, Investigator	Margaret M Annes CSO Signed By: MARGARET M. ANNES-S Date Signed: 08-28-2026 14:17:31	DATE ISSUED 8/28/2026
	X		

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

DISTRICT ADDRESS AND PHONE NUMBER 1201 Main Street, Suite 7200 Dallas, TX 75202 (214) 253-5200 Fax: (214) 253-5314	DATE(S) OF INSPECTION 8/20/2026-8/28/2026* FEI NUMBER 3045022201
---	---

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Stuart E. Tolman, R.Ph., Pharmacist-in-Charge

FIRM NAME Houston Rx LLC	STREET ADDRESS 15340 Vantage Pkwy E Ste 220
CITY, STATE, ZIP CODE, COUNTRY Houston, TX 77032-1901	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drugs

On August 3, 2026, your firm recovered 1CFU in the ISO 5 Laminar Flow Hood (b) (4) (viable surface sample) after the filling/stoppering of lot #TZN-080326-20/2-2 of Tirzepatide/Niacinamide 20/2 mg/mL (2mL vial). No investigation was performed as your firm's action level for ISO 5 areas is (b) (4) CFU, which is not appropriate. The lot was released and has been partially distributed.

OBSERVATION 6

The facility is designed and/or operated in a way that permits poor flow of personnel or materials.

Specifically, technicians enter the ISO 8 cleanroom area via a door from the unclassified (b) (4) area. Gowning occurs in the ISO 8 area, including washing of hands, on the "clean" side of the demarcation line. There is no designated room or area for gowning. Employees who are gowned and not gowned can interact in the same space while gowning. After formulation, those employees will then enter the ISO 7 cleanroom and work in the ISO 5 hood preparing sterile drug products without changing their garb except for their sterile gloves.

OBSERVATION 7

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

Specifically, on August 24, 2026, we watched the filling and stoppering of lot #SMN-082426-5/2-5 of Semaglutide/Niacinamide 5mg/2mg/1mL. Your practice is to place the sterile stoppers onto the filled vials using (b) (4) and then pressing down on the stoppers with your (b) (4) to push the stopper into the vial. You then (b) (4) of the vials with (b) (4) (b) (4) the (b) (4) and take them out of the cleanroom. They may be stored overnight in the (b) (4). (b) (4) of the vials, which is the final step to finish the closing of the vials, occurs in the unclassified area of the (b) (4).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Margaret M Annes, CSO Megan T Ziegler, Investigator	Margaret M Annes CSO Signed By: MARGARET M. ANNES-S Date Signed: 08-28-2026 14:17:31 X	DATE ISSUED 8/28/2026

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

DISTRICT ADDRESS AND PHONE NUMBER 1201 Main Street, Suite 7200 Dallas, TX 75202 (214) 253-5200 Fax: (214) 253-5314		DATE(S) OF INSPECTION 8/20/2026-8/28/2026*
		FEI NUMBER 3045022201
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Stuart E. Tolman, R.Ph., Pharmacist-in-Charge		
FIRM NAME Houston Rx LLC	STREET ADDRESS 15340 Vantage Pkwy E Ste 220	
CITY, STATE, ZIP CODE, COUNTRY Houston, TX 77032-1901	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drugs	

OBSERVATION 8

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

Specifically, typical batch sizes for Semaglutide/Niacinamide and Tirzepatide/Niacinamide drug products are (b) (4) vials. Vial sizes can range from 1mL to 5mL for GLP1 products and up to 10mL for other drug products. Production includes (b) (4) the drug product into a sterile (b) (4) filling vials from the (b) (4) of (b) (4) drug product using a (b) (4), and then manually placing stoppers on the vials. During a media fill, per your Quality Assurance/Compliance Pharmacy Technician, your firm fills (b) (4) vials. Your firm takes prepared media from a vial, draws it into a (b) (4), and then fills the vials using the (b) (4). Your firm also does not document the number of vials filled, incubated and read in the paperwork for the media fills.

OBSERVATION 9

Use of ingredients not intended for pharmaceutical use in sterile drug production.

Specifically, your firm is using active pharmaceutical ingredients and excipients that are not always USP/NF grade or are non-pharmaceutical grade. For example,

- The Certificate of Analysis (CoA) for Lot #(b) (4) of Methylcobalamin states "For R&D only". Your firm has made approximately (b) (4) lots of Methylcobalamin 5mg/mL using lot # (b) (4)
- The CoA for lot #(b) (4) of Tirzepatide states it is for "R&D only". Your firm has made approximately (b) (4) lots of Tirzepatide/Niacinamide 10/2 mg/mL and (b) (4) lots of

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Margaret M Annes, CSO Megan T Ziegler, Investigator	Margaret M Annes CSO Signed By: MARGARET M. ANNES-S Date Signed: 08-28-2026 14:17:31 X	DATE ISSUED 8/28/2026

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 1201 Main Street, Suite 7200 Dallas, TX 75202 (214) 253-5200 Fax: (214) 253-5314		DATE(S) OF INSPECTION 8/20/2026-8/28/2026* FEI NUMBER 3045022201	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Stuart E. Tolman, R.Ph., Pharmacist-in-Charge			
FIRM NAME Houston Rx LLC		STREET ADDRESS 15340 Vantage Pkwy E Ste 220	
CITY, STATE, ZIP CODE, COUNTRY Houston, TX 77032-1901		TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drugs	
Tirzepatide/Niacinamide 20/2 mg/mL using lot #(b) (4) of Tirzepatide. c) The CoA for lot #(b) (4) of Sermorelin states "This product is intended for scientific research use only". Your firm has made approximately (b) (4) lots of Sermorelin 1mg/mL using lot #(b) (4) d) The CoA for lot #(b) (4) of Semaglutide API states it is for "R&D only". Your firm has made at least (b) (4) lots of Semaglutide/Niacinamide 2.5/2 mg/mL and (b) (4) lots of Semaglutide/Niacinamide 5/2 mg/mL using lot #(b) (4) e) The CoA for lot #(b) (4) of Nicotinamide Adenine Dinucleotide+ (NAD+) states "For Laboratory Use Only!". Your firm has made at least (b) (4) of Nicotinamide Adenine Dinucleotide+ 100 mg/mL using (b) (4) f) The CoA for lot #(b) (4) of Niacinamide, USP is not pharmaceutical grade as the USP monograph is a dietary supplement monograph. Your firm uses niacinamide in all GLP1 formulations and has used this specific lot to make all Semaglutide/Niacinamide and Tirzepatide/Niacinamide for at least the last (b) (4) months.			
OBSERVATION 10 Contamination was observed in your areas adjacent to production areas. Specifically, a ceiling vent just outside the cleanroom has water stains and what appears to be mold. On August 24, 2026, the vent was dripping condensate near the area where items to be taken into the cleanroom were wiped down for use in making lot #SMN-082426-5/2-5 of Semaglutide/Niacinamide 5mg/2mg/1mL.			
SEE REVERSE OF THIS PAGE		EMPLOYEE(S) SIGNATURE Margaret M Annes, CSO Megan T Ziegler, Investigator Margaret M Annes CSO Signed By: MARGARET M. ANNES-S Date Signed: 08-28-2026 14:17:31 X _____	
		DATE ISSUED 8/28/2026	

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

DISTRICT ADDRESS AND PHONE NUMBER 1201 Main Street, Suite 7200 Dallas, TX 75202 (214) 253-5200 Fax: (214) 253-5314	DATE(S) OF INSPECTION 8/20/2026-8/28/2026* FEI NUMBER 3045022201
---	---

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Stuart E. Tolman, R.Ph., Pharmacist-in-Charge

FIRM NAME Houston Rx LLC	STREET ADDRESS 15340 Vantage Pkwy E Ste 220
CITY, STATE, ZIP CODE, COUNTRY Houston, TX 77032-1901	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drugs

OBSERVATION 11

Use of cleaning and disinfecting agents that may leave residues or not adequately rinsing such agents from containers, closures, or equipment that come into direct contact with drug products.

Specifically, your firm uses (b) (4) and tap water to wash equipment used to make sterile drug products, including glass beakers, stir bars, and graduated cylinders. Your firm rinses the equipment with (b) (4) sterile water and then wipes the beakers and stir bars with (b) (4). There is no wiping down of the inside of the graduated cylinders with (b) (4). The graduated cylinders are used to measure out liquids such as the sterile water used during the production of sterile drug products. On August 24, 2026, we watched the cleaning of equipment to be used in the making of lot #SMN-082426-5/2-5 of Semaglutide/Niacinamide 5mg/2mg/1mL, using this process.

OBSERVATION 12

Sterile products were exposed to non-sterile or non-depyrogenated supplies.

Specifically, your firm does not sterilize/depyrogenate the glass beakers, (b) (4) graduated cylinders, and stir bars used to make sterile drug products. On August 24, 2026, we watched the preparation of lot #SMN-082426-5/2-5 of Semaglutide/Niacinamide 5mg/2mg/1mL. The glass beakers, (b) (4) graduated cylinders and stir bars were not sterilized/depyrogenated before use.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Margaret M Annes, CSO Megan T Ziegler, Investigator	Margaret M Annes CSO Signed By: MARGARET M. ANNES-S Date Signed: 08-28-2026 14:17:31 X	DATE ISSUED 8/28/2026

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

DISTRICT ADDRESS AND PHONE NUMBER 1201 Main Street, Suite 7200 Dallas, TX 75202 (214) 253-5200 Fax: (214) 253-5314	DATE(S) OF INSPECTION 8/20/2026-8/28/2026* FEI NUMBER 3045022201
---	---

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Stuart E. Tolman, R.Ph., Pharmacist-in-Charge

FIRM NAME Houston Rx LLC	STREET ADDRESS 15340 Vantage Pkwy E Ste 220
CITY, STATE, ZIP CODE, COUNTRY Houston, TX 77032-1901	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drugs

OBSERVATION 13

Biological indicators were not used to verify the adequacy of the sterilization cycle.

Specifically, your firm has not validated nor do you use a biological indicator (BI) when (b) (4) the (b) (4) and (b) (4) used in the preparation of sterile drug products. The (b) (4) are used to place sterile stoppers onto the filled vials. (b) (4) are used to (b) (4) the (b) (4) of sterile water used in the formulation of sterile drug products.

OBSERVATION 14

Your firm is not storing active pharmaceutical ingredients (API) per the labeled storage conditions.

All APIs are stored in a (b) (4) refrigerator. Examples of APIs used in the production of sterile drug products that are not stored according to the labeled storage conditions include the following. Sterile drug products made with these APIs have been released and distributed.

- a) The CoA for lot # (b) (4) of Semaglutide API states to store at (b) (4). Your firm has made at least (b) (4) lots of Semaglutide/Niacinamide 2.5/2 mg/mL and (b) (4) lots of Semaglutide/Niacinamide 5/2 mg/mL using lot # (b) (4).
- b) The CoA for lot # (b) (4) of Tirzepatide API states to store at (b) (4). Your firm has made approximately (b) (4) lots of Tirzepatide/Niacinamide 10/2 mg/mL and (b) (4) lots of Tirzepatide/Niacinamide 20/2 mg/mL using lot # (b) (4) of Tirzepatide.
- c) The CoA for lot # (b) (4) of Tirzepatide API states to store at (b) (4).
- d) The CoA for lot # (b) (4) of Sermorelin API states to store at (b) (4).
- e) The CoA for lot # (b) (4) of Nicotinamide Adenine Dinucleotide+ (NAD+) states to store in (b) (4). Your firm has made at least (b) (4) of Nicotinamide

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Margaret M Annes, CSO Megan T Ziegler, Investigator	Margaret M Annes CSO Signed By: MARGARET M. ANNES-S Date Signed: 08-28-2026 14:17:31	DATE ISSUED 8/28/2026
	X		

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER

1201 Main Street, Suite 7200
Dallas, TX 75202
(214) 253-5200 Fax: (214) 253-5314

DATE(S) OF INSPECTION

8/20/2026-8/28/2026*

FEI NUMBER

3045022201

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Stuart E. Tolman, R.Ph., Pharmacist-in-Charge

FIRM NAME

Houston Rx LLC

STREET ADDRESS

15340 Vantage Pkwy E Ste 220

CITY, STATE, ZIP CODE, COUNTRY

Houston, TX 77032-1901

TYPE ESTABLISHMENT INSPECTED

Producer of Sterile Drugs

Adenine Dinucleotide+ 100 mg/mL using (b) (4)

***DATES OF INSPECTION**

8/20/2026(Thu), 8/21/2026(Fri), 8/24/2026(Mon), 8/25/2026(Tue), 8/26/2026(Wed),
8/28/2026(Fri)

X Megan T Ziegler
Investigator
Signed By: MEGAN T. ZIEGLER-S
Date Signed: 08-28-2026 14:18:01

**SEE REVERSE
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Margaret M Annes, CSO
Megan T Ziegler, Investigator

X Margaret M Annes
CSO
Signed By: MARGARET M.
ANNES-S
Date Signed: 08-28-2026
14:17:31

DATE ISSUED

8/28/2026

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."