

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER FDA 4040 North Central Expressway Suite #300 Dallas, TX 75204 214-253-5200 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 11/13-15; 18-20;25-26/2019; 12/3/2019
	FEI NUMBER 3015617746

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Mr. Raghuvveer R. Chintalapally, R.Ph. & Owner

FIRM NAME Nanobots Healthcare, LLC dba Assurance Infusion	STREET ADDRESS 2626 South Loop West #555
CITY, STATE AND ZIP CODE Houston, TX 77054	TYPE OF 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) (WE) OBSERVED:

OBSERVATION #1

Your firm does not test any lots of intrathecal drug products for endotoxin prior to release. All lots of intrathecal drug products are produced using non-sterile bulk drugs which are then (b) (4) and stored under refrigeration in syringes until use.

In addition, your firm assigns a Beyond Use Date of nine days after production for all intrathecal drug products. However, your firm has no data to substantiate the the nine day Beyond Use Date.

In the last 12 months, your firm produced approximately (b) (4) lots of intrathecal drug products which were not tested for endotoxin prior to being dispensed to patients. For example, Hydromorphone 5mg/ml, lot #10302019@35 was produced on 10/30/19 and used in Rx (b) (6) for patient (b) (6), on the same date.

OBSERVATION #2

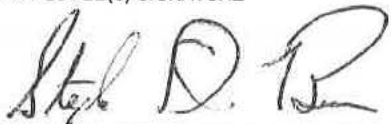
On 11/19/2019, I noted turbidity and/or precipitate in the following sterility samples:

- A. Tri-Mix lot #11112019@9
- B. Tri-Mix, lot #11112019@10
- C. Tri-Mix, lot #11112019@21

To date, your firm has not performed an investigation.

OBSERVATION #3

On 11/15/19, during the aseptic processing of Morphine 5mg/ml for Injection, lot #11132019@16, an operator

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was observed placing his gloved hands outside the ISO 5 area to retrieve supplies. Upon re-entry into the ISO 5 hood with the supplies, he failed to re-sanitize his hands. The same operator was observed with the skin of his forehead partially exposed. The operator was observed introducing the exposed skin of his forehead inside the ISO 5 hood.

OBSERVATION #4

The ISO 5 classified area was not certified under dynamic conditions. Specifically, smoke studies were not conducted to demonstrate unidirectional airflow and sweeping action over and away from sterile drug products under dynamic conditions during the last certification.

OBSERVATION #5

Your firm does not have sterility testing data to support an assigned BUD of up to 90 days for intrathecal stock solutions. For example, the stock solution for Hydromorphone HCl is assigned a BUD of 90 days after production.

OBSERVATION #6


SOP # 3.020 entitled, "Cleaning and Maintenance of the Clean Room Facility" (Effective date: 11/9/15) does not identify the contact time used for various disinfectants including (b) (4) and (b) (4). In addition, there is no documentation to substantiate the (b) (4) contact time currently in use.

OBSERVATION #7

Your firm uses an (b) (4) for the depyrogenation of glassware used in the production of sterile, injectable drug products. The (b) (4) used for depyrogenation (b) (4) has never been verified. In addition, a biological indicator has never been used to verify the adequacy of the depyrogenation process.

OBSERVATION #8

Media fills are not performed that closely simulate aseptic production operations, incorporating, as appropriate,

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worst case activities and conditions that provide a challenge to aseptic operations.

Specifically, your log sheet for conducting a high risk media fill challenge documents that a total of (b)(4) 20 ml vials (b)(4) for control and (b)(4) for evaluation) will be used to conduct media fills. Review of media fills conducted since 7/18 revealed that the media fills were not representative in that your firm failed to simulate actual production processes.

For example, your firm produced Tri-Mix Forte 30mg/2mg/20mcg/ml for Injection, lot #07272019@12 on 7/26/2019 with a batch size of approximately (b)(4) vials.

OBSERVATION #9

The wipers placed on the work surface inside the ISO 5 hood during production are not sterile. The wipers are used for the placement of (b) (4) used in production.

OBSERVATION #10

Your integrity testing device (Manufacturer: (b) (4)) has not been calibrated since 2015. The manufacturer's recommendation for re-calibration is annually.

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