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	4/20/2026-5/7/2026* FEI NUMBER 3027507354

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Laura Martin, CEO

FIRM NAME	STREET ADDRESS
Turbare Manufacturing	925 Jeanette Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Conway, AR 72032-6651	Outsourcing facility

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 responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically,

1A. Your Quality Unit failed to:

a. Ensure the timely implementation of corrective and preventive actions for the observed dried and cracked (b)(4) settle plates used for environmental monitoring and then incubated in a (b)(4) incubator. Please refer to OBSERVATION 1B.

b. Conduct adequate root-cause analyses for the ongoing Environmental Monitoring (EM) and Personnel Monitoring (PM) excursions. The Quality unit also failed to perform effectiveness checks on the implemented corrective and preventive actions, as evident by persistent fungal and bacterial recoveries despite implementing corrective actions in the clean room areas. Please refer to OBSERVATION 2 and OBSERVATION 3.

c. Investigate the root cause of visual inspection failure during initial 100% inspection before proceeding to secondary/tertiary inspection of the filled syringes. Please refer to OBSERVATION 4.

d. Evaluate air flow patterns under dynamic conditions in all ISO 5 classified BSC cabinets in the clean room. Please refer to OBSERVATION 3.

AMENDMENT 2

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1B. Your firm's quality unit failed to ensure the timely implementation of corrective and preventive actions for dried and cracked (b)(4) media settle plates.

The firm uses these (b)(4) plates for environmental monitoring in clean room areas as settle plates. After the plates are exposed for (b)(4), the plates are collected and incubated at (b)(4) in **incubator #** (b)(4) Upon removal from (b)(4) incubator some of these plates are found to be desiccated and cracked.

Your firm identified this issue and initiated a Product Quality Event-PQE-25-0085 on September 10, 2025. Several cracked plates were sent to a contract laboratory for growth promotion testing. The growth promotion testing passed and the PQE-25-0085 was closed on October 9, 2025.

The PQE-25-0085 summary report prepared by the firm shows the drying and cracking of the media plates is due to low humidity levels within the (b)(4) incubator. Your humidity monitoring equipment installed in the incubator confirmed that humidity levels consistently fell below the recommended (b)(4) level.

The incubator averaged 57%, dipping as low as 26.6% on days when the incubator door was opened frequently. It took multiple days for humidity to return to the average level of approximately 57%.

It must be noted that the growth promotion test does not make the Incubator # (b)(4) fit for use. Growth promotion test uses a low inoculum of (b)(4), which is a controlled, ideal-condition challenge. This does not replicate the real-world conditions of passive air sampling (settle plates), where organisms may be stressed, desiccated, or present in very low numbers.

I observed three (3) cracked plates which were incubated on April 16, 2026, and read in front of me on April 24, 2026. Two plates were used for environmental monitoring in (b)(4), and one plate was used in (b)(4) during compounding operations.

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Your microbiologist stated that she normally observes cracked plates once or twice a week during reading. To this date, effective corrective actions has not been implemented.

Your acknowledgment of the problem for over nine months, combined with a lack of executed corrective actions, shows the quality system is not functioning effectively to address the identified deficiencies in a timely manner.

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not followed.

Specifically,

2A. Your firm's environmental monitoring program failed to prevent or adequately address repeated fungal (mold) contamination in ISO Class 7 and ISO Class 8 classified areas within the same cleanroom (b) (4) that support aseptic compounding operations conducted in ISO Class 5 Primary Engineering Controls.

The environmental monitoring data collected between July 2025 and April 2026 document at least **nineteen (19)** separate fungal excursion events across ISO 8 rooms (Rooms (b) (4)) representing a recurring and unresolved pattern of mold contamination in the classified cleanroom environment supporting aseptic compounding operations.

The following is the list of nineteen (19) documented fungal contamination events in the clean room area:

Investigation #	Date Opened	Date Closed	Room / ISO Class	CFU Count	Organism(s) Identified

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EME-25-0046	2025-07-22	2025-09-09	Room (b)(4)	ISO 8	1 CFU	Periconia sp.
EME-25-0055	2025-07-31	2025-09-11	Room	ISO 8	1 CFU (3 total)	Cladosporium cladosporioides
EME-25-0056	2025-07-31	2025-09-11	Room	ISO 8	1 CFU	Parengyodontium album
EME-25-0057	2025-07-31	2025-09-19	Room	ISO 8	1 CFU	Penicillium parvulum
EME-25-0087	2025-09-12	2025-10-17	Room	ISO 8	1 CFU (2 total)	Cladosporium spp. (multiple species)
EME-25-0088	2025-09-15	2025-10-22	Room	ISO 8	1 CFU (2 total)	Pseudopithomyces palmicola
EME-25-0089	2025-09-16	2025-10-17	Room	ISO 8	1 CFU (3 total)	Parengyodontium album
EME-25-0096	2025-09-26	2025-10-24	Room	ISO 8	1 CFU	Talaromyces wortmannii
EME-25-0097	2025-09-29	2025-12-11	Room	ISO 7	2 CFU	Curvularia geniculata/senegalensis
EME-25-0107	2025-10-15	2025-11-05	Room	ISO 8	2 CFU (6 total)	Engyodontium rectidentatum
EME-25-0114	2025-10-21	2025-12-11	Room	ISO 7	2 CFU	Cladosporium spp. (multiple species)
EME-25-0130	2025-11-04	2025-12-11	Room	ISO 8	1 CFU	Microsphaeropsis arundinis
EME-25-0156	2025-12-03	2026-01-30	Room	ISO 8	1 mold CFU (19 total)	Penicillium decaturense (+ bacterial co-recoveries)
EME-25-0179	2025-12-29	2026-02-06	Room	ISO 8	1 CFU	Mold – unidentified (b)(4)
EME-26-0036	2026-02-02	2026-03-18	Room	ISO 8	2 mold CFU (5 total)	Cladosporium spp.; Stachybotrys chlorohalonata
EME-26-0037	2026-02-02	2026-03-13	Room	ISO 7	1 CFU	Cladosporium halotolerans
EME-26-0058	2026-02-18	2026-03-18	Room	ISO 8	1 mold CFU (12 total)	Epicoccum nigrum (+ bacterial co-recoveries)
EME-26-0119	2026-03-30	**Still Open**	Room	ISO 7	1 CFU	Alternaria alternata
EME-26-0128	2026-04-02	**Still Open**	Room	ISO 8	1 CFU (3 total)	Beauveria bassiana

Over **Sixteen (16)** distinct fungal species were recovered across the monitoring period spanning July 2025 through April 2026. The isolates included environmental molds (*Cladosporium, Penicillium, Alternaria, Curvularia*), opportunistic pathogens (*Beauveria bassiana, Parengyodontium album*), mold *Stachybotrys chlorohalonata* which may be toxigenic.

Despite implementation of corrective actions - including revisions to SOP-038 (Gowning and Handwashing Procedures), personnel retraining, and modification of the material sanitization process to incorporate a sporicidal agent - fungal contamination events have continued to recur through April 2026. It demonstrates an unresolved contamination trend despite repeated corrective actions.

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For investigation EME-25-0156, the firm documented no corrective action for a 19 CFU recovery event that included mold (*Penicillium decaturense*), citing ISO 8 gowning requirements as justification, without adequate assessment of risk to product quality.

As of current inspection, at least **five (5)** fungal contamination investigations remain open and unresolved, including four consecutive fungal recovery events documented in Room (b)(4) (ISO 8) within a 12-day period (March 27-April 8, 2026).

The environmental samples are always taken from the designated sites which were chosen during the initial risk assessment. No additional samples are taken to verify the extent and source of fungal contamination.

The recurrence of fungal contamination in ISO 7 and ISO 8 classified areas, which directly support operations in ISO 5 Primary Engineering Controls, poses a risk to the sterility of compounded drug products.

2B. Your firm has not performed dynamic smoke studies for all biological safety cabinets (BSCs) used in the manufacturing of sterile drug products as part of periodic requalification. Your clean room area has a total of (b)(4) ISO 5 biological safety cabinets. Clean Room(b)(4) has (b)(4) and Clean Room(b)(4) has (b)(4) biological safety cabinets which are all actively used for compounding drug products.

Your firm has conducted (b) (4) smoke studies since February 2024.

1. In Clean Room (b) (4) which is in use, both static and dynamic smoke studies were conducted for biological safety cabinets (b)(4) on Feb 20, 2024.
2. In Clean Room (b) (4) static and dynamic smoke studies were conducted (b)(4) and static studies were conducted on (b)(4) on Dec 30, 2025.

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3. Dynamic and static smoke studies have been conducted on (b)(4) from Feb 20 to Jul 1, 2025.

4. However Dynamic smoke studies were never conducted after Feb 20, 2024, on (b)(4), only static studies were performed.

   Since Nov 2025 in (b)(4), a total of (b)(4) lots were compounded (Avastin (b)(4) Vancomycin (b)(4) and in (b)(4) a total of (b)(4) Avastin lots were compounded.

   Failure to perform periodic requalification of your dynamic smoke studies on all ISO 5 biological safety cabinets used in sterile compounding operations does not provide assurance that these units maintain appropriate environmental conditions to prevent contamination of sterile drug products.

OBSERVATION 3

Production personnel were not practicing good sanitation and health habits.

Specifically,

Your firm failed to establish and maintain adequate controls to prevent repeated objectionable microorganism recoveries during personnel monitoring (PM) activities in ISO Class 5 and ISO Class 7 classified areas.

Environmental monitoring records document **six (6)** personnel monitoring excursion events involving bacterial contamination from personnel gowning samples (chest, forehead, forearm) and fingertip samples collected between April 2025 and February 2026.

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Multiple excursions involved objectionable gram-negative organisms. The assigned root causes were generally insufficient aseptic gowning technique, improper material transfer, cleaning or personnel movement.

The following is the list of six (6) documented contamination events:

Investigation #	Date of Sample	Operator / Sample Type	Room / ISO Class	CFU Count	Organism(s) Identified	Lot Impacted	Units Rejected	Root Cause
EM-25-001 **NCR-25-013**	16 Apr 2025	(b)(4) Chest	Room (b)(4) / ISO 7	15 CFU	*Corynebacterium segmentosum* *Actinomyces oris/naeslundii* *Staphylococcus epidermidis* *Staphylococcus capitis*	0416202(b)(4)	(b) (4)	Ineffective aseptic technique during gowning and personnel movement
EM-25-002 **NCR-25-014**	21 Apr 2025	(b)(4) Chest	Room (b)(4) / ISO 7	5 CFU	*Staphylococcus capitis*	0421202(b)(4)		Insufficient aseptic gowning technique
EM-25-003	06 May 2025	(b)(4) Chest & Forehead	Room (b)(4) / ISO 7	7 CFU	*Staphylococcus capitis* *Staphylococcus cohnii* *Corynebacterium ureicelerivorans*	0506202(b)(4)		Ineffective aseptic technique during gowning and personnel movement
EM-25-004	08 May 2025	(b)(4) Chest	Room (b)(4) / ISO 7	3 CFU	*Staphylococcus hominis*	0508202(b)(4)	QA stopped production	Insufficient aseptic gowning, (b)(4) contact time not achieved (Repeat operator: (b)(6), (b)(7)(C))
EME-25-0017	28 May 2025	(b)(4) Chest	Room (b)(4) / ISO 7	2 CFU	*Proteus mirabilis/vulgaris/hauseri*	0528202(b)(4)	(b) (4)	Insufficient material transfer execution; insufficient aseptic gowning technique
EME-25-0155	20 Nov 2025	(b)(4) Forearm	Room (b)(4) / ISO 7	5 CFU	*Micrococcus luteus* *Moraxella osloensis* *Brevundimonas sp.*	MBPAQ-25-IQ003 (Media Fill)	N/A	Gowning practices and/or personnel movement

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Multiple operators were involved in repeated excursion events following the same root causes, and several operators (b) (6), (b) (7)(C) appeared in more than one investigation.

Despite corrective actions including personnel retraining and SOP revisions, bacterial contamination during personnel monitoring continued to recur throughout the observation period. The excursions occurred in ISO Class 5 and ISO Class 7 environments-indicating the implemented corrective actions were ineffective.

Furthermore, the recovery of objectionable gram-negative organisms (*Proteus mirabilis/vulgaris/hauseri, Moraxella osloensis*) from personnel gowning samples represents a heightened risk to product sterility, as these organisms are not part of normal skin flora and indicate a failure in environmental and personnel hygiene control.

OBSERVATION 4

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

Your firm failed to conduct, or document, an investigation into the root cause of visual inspection failures prior to proceeding with secondary and/or tertiary inspections.

A review of ophthalmic lot visual inspection records spanning from March 2025 through early 2026 identified **forty-four (44)** lots in which the firm proceeded directly to secondary inspection following a primary visual inspection failure which was characterized by major reject rates exceeding the (b)(4) acceptance limit and/or major defects found at the primary AQL stage. There was no documented investigation and root cause analysis into the source and cause of these recurring defect types prior to reinspection.

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In addition, 2 lots (09262025(b) (4) and 0101-01-26-0067) proceeded to tertiary inspection after secondary inspection also failed, without a documented investigation of initial 100% visual inspection failure. The predominant defect types identified were intrinsic particulate and product fill volume defects.

The table below shows details of all the **44** lots:

Lot Number	Inspection Stage Failed	Failure Reason	Key Defects	Proceeded To	Investigation Documented?
03032025(b) (4)	Primary VI	Major reject	23 Product Fill Volume, 2 Intrinsic Particle	Secondary	No
03052025(b) (4)	Primary VI	Major reject	29 Product Fill Volume, 3 Intrinsic Particle	Secondary	No
06112025(b) (4)	Primary VI	Major reject	37 Intrinsic Particle, 9 Product Fill Volume	Secondary	No
06202025(b) (4)	Primary VI	Major reject	10 Product Fill Volume, 38 Intrinsic Particle	Secondary	No
06252025(b) (4)	Primary VI	Major reject	37 Intrinsic Particle, 6 Product Fill Volume	Secondary	No
07182025(b) (4)	Primary AQL	5 Major defects at AQL	5 Intrinsic Particle	Secondary	No
07242025(b) (4)	Primary VI	Major reject	17 Intrinsic Particle, 11 Product Fill Volume	Secondary	No
08252025(b) (4)	Primary VI	Major reject	41 Intrinsic Particle	Secondary	No
09042025(b) (4)	Primary VI	Major reject	49 Intrinsic Particle, 15 Product Fill Volume	Secondary	No
09102025(b) (4)	Primary VI	Major reject	10 Product Fill Volume, 38 Intrinsic Particle	Secondary	No
09182025(b) (4)	Primary AQL	3 Major defects at AQL	3 Intrinsic Particle	Secondary	No
09192025(b) (4)	Primary AQL	8 Major defects at AQL	8 Intrinsic Particle	Secondary	No
09232025(b) (4)	Primary AQL	3 Major defects at AQL	1 Product Fill Volume, 2 Intrinsic	Secondary	No

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			Particle		
09242025(b)(4)	Primary AQL	3 Major defects at AQL	3 Intrinsic Particle	Secondary	No
09252025(b)(4)	Primary AQL	2 Major defects at AQL	2 Intrinsic Particle	Secondary	No
09252025(b)(4)	Primary VI	Major reject (b)(4)	27 Intrinsic Particle, 11 Product Fill Volume	Secondary	No
09262025(b)(4) ★	Primary AQL & Secondary VI	AQL: 2 Major; Secondary: Major rejects(b)(4) (NCR-25-0104)	2 Intrinsic Particle; 4 PFV, 32 Intrinsic Particle	Secondary & Tertiary	No
09262025(b)(4)	Primary AQL	6 Major defects at AQL	6 Intrinsic Particle	Secondary	No
09292025(b)(4)	Primary AQL	2 Major defects at AQL	2 Intrinsic Particle	Secondary	No
10022025(b)(4)	Primary VI	Major rejects (b)(4)	4 Product Fill Volume, 32 Intrinsic Particle	Secondary	No
10072025(b)(4)	Primary VI	Major rejects	4 Product Fill Volume, 42 Intrinsic Particle	Secondary	No
10092025(b)(4)	Primary VI	Major rejects	3 Product Fill Volume, 29 Intrinsic Particle	Secondary	No
10102025(b)(4)	Primary VI	Major rejects	3 Product Fill Volume, 40 Intrinsic Particle	Secondary	No
10102025(b)(4)	Primary VI	Major rejects	34 Intrinsic Particle, 4 Product Fill Volume	Secondary	No
10152025(b)(4)	Primary VI	Major rejects	2 Product Fill Volume, 33 Intrinsic Particle	Secondary	No
10202025(b)(4)	Primary VI	Major rejects	9 Product Fill Volume, 33 Intrinsic Particle	Secondary	No
10212025(b)(4)	Primary VI	Major rejects	20 Product Fill Volume, 16 Intrinsic Particle	Secondary	No
10222025(b)(4)	Primary VI	Major rejects	13 Product Fill Volume, 16 Intrinsic Particle	Secondary	No
10242025(b)(4)	Primary VI	Major rejects	13 Product Fill Volume, 18	Secondary	No

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			Intrinsic Particle		
11042025[(b)(4)]	Primary VI	Major rejects (b)(4)	2 Product Fill Volume, 30 Intrinsic Particle	Secondary	No
11052025[(b)(4)]	Primary VI	Major rejects	7 Product Fill Volume, 35 Intrinsic Particle	Secondary	No
11142025[(b)(4)]	Primary VI	Major rejects	23 Product Fill Volume, 14 Intrinsic Particle	Secondary	No
11242025[(b)(4)]	Primary VI	Major rejects	8 PFV, 1 Cap Defect, 30 Intrinsic Particle	Secondary	No
12012025[(b)(4)]	Primary VI	Major rejects	8 PFV, 1 Cap Defect, 17 Intrinsic Particle	Secondary	No
12192025[(b)(4)]	Primary AQL	3 Major defects at AQL	3 Product Fill Volume	Secondary	No
0101-01-26-0022	Primary VI	Major reject (b)(4)	28 Product Fill Volume, 18 Intrinsic Particulate	Secondary	No
0101-01-26-0023	Primary VI	Major reject	41 Product Fill Volume, 15 Intrinsic Particulate	Secondary	No
0101-01-26-0030	Primary VI	Major reject	17 Product Fill Volume, 33 Intrinsic Particulate	Secondary	No
0101-01-26-0043	Primary VI	Major reject	14 Product Fill Volume, 32 Intrinsic Particulate	Secondary	No
0101-01-26-0047	Primary VI	Major reject	15 Product Fill Volume, 31 Intrinsic Particulate	Secondary	No
0101-01-26-0048	Primary VI	Major reject	12 Product Fill Volume, 34 Intrinsic Particulate	Secondary	No
0101-01-26-0067 ★	Primary VI & Secondary VI	VI(b) (4) Secondary: 4 Major (NCR-26-0094)	33 PFV, 25 Intrinsic; then 4 PFV at secondary	Secondary & Tertiary	No
0101-01-26-0068	Primary VI	Major rejects (b)(4)	51 Product Fill Volume, 24 Intrinsic Particulate	Secondary	No
0101-01-26-0075	Primary VI	Major rejects	33 Product Fill Volume, 37 Intrinsic Particulate	Secondary	No
0101-01-26-0080	Primary VI	Major rejects	30 Product Fill Volume, 26	Secondary	No

AMENDMENT 2

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Sangeeta M Khurana, Investigator-GDUFA

X Sangeeta M Khurana Investigator-GDUFA Signed By: SANGEETA M. KHURANA -S Date Signed: 05-27-2026 14:47:41

DATE ISSUED
5/27/2026

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	4/20/2026-5/7/2026*
	FEI NUMBER 3027507354

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Laura Martin, CEO

FIRM NAME	STREET ADDRESS
Turbare Manufacturing	925 Jeanette Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Conway, AR 72032-6651	Outsourcing facility

			Intrinsic Particulate		

This is a Repeat Observation

*DATES OF INSPECTION

4/20/2026(Mon), 4/21/2026(Tue), 4/22/2026(Wed), 4/23/2026(Thu), 4/24/2026(Fri), 4/27/2026(Mon), 4/28/2026(Tue), 4/29/2026(Wed), 4/30/2026(Thu), 5/01/2026(Fri), 5/07/2026(Thu)

AMENDMENT 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Sangeeta M Khurana, Investigator-GDUFA	X Sangeeta M Khurana Investigator-GDUFA Signed By: SANGEETA M. KHURANA -S Date Signed: 05-27-2026 14:47:41	5/27/2026

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."