DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483responses@fda.hhs.gov	April 7th -17th, 2026
	FEI NUMBER 3004086192

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Shankar R Mohole, General Manager Production	
FIRM NAME USV Private Limited	STREET ADDRESS H-13, 16, 16A, 17, 18, 19, 20, 21 & E-22, OIDC, Mahatma Gandhi Udyog Nagar Road
CITY, STATE, ZIP CODE, COUNTRY Dabhel, Daman, Daman And Diu, 396210 India	TYPE ESTABLISHMENT INSPECTED Sterile (b) (4) Drug Manufacturer

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

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

Specifically,

A. During filling of (b) (4) on the (b) (4) line for protocol DMF/MSP/26/016 "Protocol for filling of (b) (4) in (b) (4) mL (b) (4) Bottle in (b) (4) Bottle)" Filling line, poor aseptic practices were obs(4)ved:

1. An operator was observed breaching first air by reaching over open sterile bottles near the (b) (4) (b) (4) during the replacement of viable air sampling plates. The bottles exposed during this breach were not removed from the line. During this intervention, the RABS (b) (4) was (b) (4) a Grade B environment and (b) (4) operator, gowned to Grade B standards, performed a sanitization procedure on the (b) (4) which was (b) (4) into the Grade B zone. This procedure involved wiping the sterilized (b) (4) with (b) (4), which removes the (b) (4) validated sterile state, rendering it only sanitized. This sanitization was further compromised when the

SEE REVERSE OF THIS PAGE	Lisa L. Flores, Investigator Rafeeq A. Habeeb, Investigator	Lisa L. Flores -S Digitally signed by Lisa L. Flores -S Date: 2026.04.17 11:43:39 +05'30' RAFEEQ HABEEB -S Digitally signed by RAFEEQ HABEEB -S Date: 2026.04.17 11:40:28 +05'30'	April, 17th 2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483responses@fda.hhs.gov	April 7th -17th, 2026
	FEI NUMBER 3004086192

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Shankar R Mohole, General Manager Production	
FIRM NAME USV Private Limited	STREET ADDRESS H-13, 16, 16A, 17, 18, 19, 20, 21 & E-22, OIDC, Mahatma Gandhi Udyog Nagar Road
CITY, STATE, ZIP CODE, COUNTRY Dabhel, Daman, Daman And Diu, 396210 India	TYPE ESTABLISHMENT INSPECTED Sterile (b) (4) Drug Manufacturer

operator's forearm and hand passed directly over the (b) (4), obstructing first air. This was not recreated in either smoke study in (b) (4)

2. An operator placed a forceps adjacent to the fill line in a manner that caused the forceps to lean over open bottles containing product, thereby obstructing first air. The bottles exposed during this breach were not removed from the line.

3. First air was breached over open product containers when the operator made multiple adjustments to the (b) (4) during active filling operations. The bottles exposed during these breaches were not removed from the line.

4. During execution of the qualified intervention "Bottle Fall on Conveyor Belt Removed by a Technician with Forceps," an operator successfully removed the first fallen bottle using forceps but when he was pushing the line of vials forward towards the (b) (4), a second bottle fell during the intervention process. Instead of removing the second fallen bottle, the operator stood the bottle upright and pushed it toward the (b) (4) using forceps.

B. During manufacturing of (b) (4) Injection (b) (4) mcg/mL, batch (b) (4), an aseptic connection was performed between the (b) (4) tank and (b) (4) tubing leading to the (b) (4) tank. Despite this representing the highest risk operation for microbial contamination, the batch manufacturing record does not document when the connection was performed, its duration, or which personnel performed it. Additionally, no finger dabs are collected after this aseptic connection, and the operator performing the connection inside the Grade A area is gowned only to Grade B standards.

C. During set-up and filling operations, the following equipment and materials were transferred between Grade B and Grade A areas without adequate sanitization:

SEE REVERSE OF THIS PAGE	Lisa L. Flores, Investigator Rafeeq A. Habeeb, Investigator	LLF RAH	April, 17th 2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483responses@fda.hhs.gov	April 7th -17th, 2026
	FEI NUMBER 3004086192

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Shankar R Mohole, General Manager Production	
FIRM NAME USV Private Limited	STREET ADDRESS H-13, 16, 16A, 17, 18, 19, 20, 21 & E-22, OIDC, Mahatma Gandhi Udyog Nagar Road
CITY, STATE, ZIP CODE, COUNTRY Dabhel, Daman, Daman And Diu, 396210 India	TYPE ESTABLISHMENT INSPECTED Sterile (b) (4) Drug Manufacturer

1. For (b) (4) Injection (b) (4) mcg/mL, batches (b) (4) (b) (4) containers: (b) (4) used for sanitization were observed being transferred between Grade B and Grade A areas without sanitization of the exterior surfaces of the containers. These containers were used held directly over the Doctor's hands. The Doctor is the person responsible for all assembly practices within the RABS (b) (4)
2. For (b) (4) Injection (b) (4) mcg/mL, batch (b) (4) a (b) (4) used to transport environmental monitoring settle plates was moved between Grade B and Grade A areas. This (b) (4) was not sanitized before entering the Grade A environment.

OBSERVATION 2

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.

Specifically,

Aseptic processing operations fail to provide adequate protection of Grade A (ISO Class 5) environments and first air over critical exposure points.

For example:

A. Rooms (b) (4) (Vial Filling and Sealing) and (b) (4) Filling): Grade A (b) (4) laminar airflow areas are separated from Grade B areas solely by an incomplete (b) (4) (approximately (b) (4) (b) (4) barrier (b) (4) . This barrier design is fundamentally inadequate to prevent air migration and cross-contamination from Grade B into Grade A areas because:

SEE REVERSE OF THIS PAGE	Lisa L. Flores, Investigator Rafeeq A. Habeeb, Investigator	LLF RAH	April, 17th 2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483responses@fda.hhs.gov	April 7th -17th, 2026
	FEI NUMBER 3004086192

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Shankar R Mohole, General Manager Production	
FIRM NAME USV Private Limited	STREET ADDRESS H-13, 16, 16A, 17, 18, 19, 20, 21 & E-22, OIDC, Mahatma Gandhi Udyog Nagar Road
CITY, STATE, ZIP CODE, COUNTRY Dabhel, Daman, Daman And Diu, 396210 India	TYPE ESTABLISHMENT INSPECTED Sterile (b) (4) Drug Manufacturer

- The (b) (4) barrier does not provide complete physical separation between Grade A and Grade B areas
- Both Grade A and Grade B areas are maintained at the same pressure (b) (4) pascals), with no pressure differential to ensure unidirectional airflow from the more critical Grade A area to the less critical Grade B area
- The combination of incomplete physical separation and absence of pressure cascade allows unrestricted air exchange between classified areas, failing to protect Grade A environments from Grade B contamination
- The design provides no assurance that particulates, microorganisms, or other contaminants from the Grade B environment cannot migrate into the Grade A area where sterile products and components are exposed

B. Room (b) (4) Filling Line): After leaving the sterile bottle bowl, sterile open bottles travel approximately (b) (4) on a (b) (4) transfer belt that is only sanitized (not sterilized). This conveyor passes directly under a conveyor power box containing electrical connections. The bottles then enter a (b) (4) bottle chute where they travel approximately (b) (4) before entering a (b) (4) which moves them to another conveyor track and on to the filling station. This design prevents unidirectional laminar airflow from reaching the open bottle tops throughout the (b) (4) transport pathway, exposes sterile containers to sanitized (not sterile) equipment for approximately (b) (4) (approximately (b) (4) places non-sterile equipment directly above open sterile containers, and traps any particles generated by moving conveyor mechanisms in (b) (4) spaces with the sterile bottles. Your firm has not validated through airflow visualization studies that this design provides adequate first air protection or that sanitization of the (b) (4) track and conveyor systems is sufficient to prevent contamination of sterile bottles during this (b) (4) transport where continuous Grade A protection is blocked.

SEE REVERSE OF THIS PAGE	Lisa L. Flores, Investigator Rafeeq A. Habeeb, Investigator	LLF RAH	April, 17th 2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483responses@fda.hhs.gov	April 7th -17th, 2026
	FEI NUMBER 3004086192

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Shankar R Mohole, General Manager Production	
FIRM NAME USV Private Limited	STREET ADDRESS H-13, 16, 16A, 17, 18, 19, 20, 21 & E-22, OIDC, Mahatma Gandhi Udyog Nagar Road
CITY, STATE, ZIP CODE, COUNTRY Dabhel, Daman, Daman And Diu, 396210 India	TYPE ESTABLISHMENT INSPECTED Sterile (b) (4) Drug Manufacturer

These design deficiencies fail to ensure that aseptic processing operations adequately protect sterile drug products from environmental contamination during critical manufacturing steps.

OBSERVATION 3

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic process.

Specifically, airflow visualization studies (smoke studies) do not demonstrate appropriate airflow patterns. Additionally, airflow visualization studies and media fills fail to represent actual commercial manufacturing conditions:

A. Your airflow visualization studies do not include adequate evaluation of airflow patterns during transitions of personnel, materials, and equipment between Grade B and Grade A environments within the manufacturing suite:

   1. During the manufacturing of (b) (4) Injection (b) (4) mcg/mL, Batches (b) (4) (b) (4) in room (b) (4) Vial Filling & Capping Room (b) (4) operators were observed moving materials and equipment between the Grade B and Grade A sides of this barrier. The airflow visualization studies did not evaluate whether these transitions across the barrier maintain unidirectional airflow to prevent contamination of the Grade A area from the adjacent Grade B environment.

   2. During the filling of (b) (4) Bottle Collection Protocol for (b) (4) in (b) mL (b) (4) Bottle on (b) (4) Filling Line (DMF/MSP/26/016) in room (b) (4) Filling (b) (4)

SEE REVERSE OF THIS PAGE	Lisa L. Flores, Investigator Rafeeq A. Habeeb, Investigator	LLF RAH	April, 17th 2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483responses@fda.hhs.gov	April 7th -17th, 2026
	FEI NUMBER 3004086192

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Shankar R Mohole, General Manager Production	
FIRM NAME USV Private Limited	STREET ADDRESS H-13, 16, 16A, 17, 18, 19, 20, 21 & E-22, OIDC, Mahatma Gandhi Udyog Nagar Road
CITY, STATE, ZIP CODE, COUNTRY Dabhel, Daman, Daman And Diu, 396210 India	TYPE ESTABLISHMENT INSPECTED Sterile (b) (4) Drug Manufacturer

(b) (4), operators were observed moving materials and equipment between the Grade B and Grade A sides of this barrier. The airflow visualization studies did not evaluate whether these transitions across the (b) (4) barrier maintain unidirectional airflow to prevent contamination of the Grade A area from the adjacent Grade B environment.

B. Your airflow visualization studies fail to represent the most challenging conditions that occur during routine commercial production. Specifically:

1. During commercial manufacturing of (b) (4) Injection (b) (4) mcg/mL, Batch (b) (4) multiple operators were observed working simultaneously in the Grade B and Grade A areas performing aseptic connections, material transfers, and equipment adjustments. However, your airflow visualization studies only simulated these activities using (b) (4) operators, failing to evaluate the impact of multiple personnel on airflow patterns and potential air disruption in critical zones.

2. Your airflow visualization studies demonstrate inconsistencies in the evaluation of aseptic connections between different study versions, and fail to include all critical aseptic connections performed during every commercial batch:
   a. During your (b) (4) airflow visualization study, the aseptic connection between the sterile tubing and the (b) (4) tank attached to the manifold was performed and evaluated as an intervention; however, during your (b) (4) airflow visualization study, this same aseptic connection was not performed or evaluated, despite this connection being made during every commercial batch, including (b) (4) Injection (b) (4) mcg/mL, Batches (b) (4) This omission eliminates assessment of airflow patterns during a critical sterile operation that involves removal of sterile wrapping

SEE REVERSE OF THIS PAGE	Lisa L. Flores, Investigator Rafeeq A. Habeeb, Investigator	LLF RAH	April, 17th 2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483responses@fda.hhs.gov	April 7th -17th, 2026
	FEI NUMBER 3004086192

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Shankar R Mohole, General Manager Production	
FIRM NAME USV Private Limited	STREET ADDRESS H-13, 16, 16A, 17, 18, 19, 20, 21 & E-22, OIDC, Mahatma Gandhi Udyog Nagar Road
CITY, STATE, ZIP CODE, COUNTRY Dabhel, Daman, Daman And Diu, 396210 India	TYPE ESTABLISHMENT INSPECTED Sterile (b) (4) Drug Manufacturer

from connection ports, manipulation of sterile tubing, and direct exposure of product contact surfaces in the Grade A environment.

b. During your (b) (4) airflow visualization study, portions of the aseptic connection of the (b) (4) tubing connecting the (b) (4) tank to the product (b) (4) tank were evaluated; however, the complete intervention was not simulated. Specifically, the passing of the sterile tubing under the filling line was not included in the smoke study evaluation. During your (b) (4) airflow visualization study, this aseptic connection was not simulated or evaluated at all, despite this complete aseptic connection being performed during commercial manufacturing of all batches on the vial filling line including (b) (4) Injection (b) (4) mcg/mL, Batches (b) (4) including passing sterile tubing under the filling line.

C. Turbulent and non-unidirectional airflow observed during smoke studies: Review of airflow visualization study videos revealed instances of turbulent airflow and smoke eddying in critical Grade A areas:

1. During Video VI-02 (Machine Setup (b) (4) Tank Assembly), at timestamp (b) (4), wisps of smoke were observed curling upwards and exiting the (b) (4) LAF Grade A area, indicating a loss of unidirectional flow.
2. During Video VI-04 (Machine Setup Stoppering Assembly), at timestamp (b) (4), smoke was observed moving in an upward direction between the operators and the stopper bowl in the (b) (4) LAF Grade A area, which is contrary to the expected downward laminar flow.

D. Your airflow visualization studies demonstrate poor aseptic technique and failure to protect sterile product contact surfaces.

SEE REVERSE OF THIS PAGE	Lisa L. Flores, Investigator Rafeeq A. Habeeb, Investigator	LLF RAH	April, 17th 2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483responses@fda.hhs.gov	April 7th -17th, 2026
	FEI NUMBER 3004086192

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Shankar R Mohole, General Manager Production	
FIRM NAME USV Private Limited	STREET ADDRESS H-13, 16, 16A, 17, 18, 19, 20, 21 & E-22, OIDC, Mahatma Gandhi Udyog Nagar Road
CITY, STATE, ZIP CODE, COUNTRY Dabhel, Daman, Daman And Diu, 396210 India	TYPE ESTABLISHMENT INSPECTED Sterile (b) (4) Drug Manufacturer

1. During Video VI-21 (Re-fixing of (b) (4) Tube to (b) (4) of (b) (4)), at timestamp (b) (4) , an operator's (b) (4) forearm was observed directly over the open (b) (4)
2. During the loading of sterile components (Videos VI-09, OI-07, OI-08, and OI-09), the (b) (4) packaging was held directly over the open (b) (4) obstructing protective first air. Furthermore, this (b) (4) packaging, which had been exposed in an unqualified area, was observed making direct contact with the inner, sterile surfaces of the (b) (4)
3. During Video VI-05 (Machine Setup Sealing Assembly), at timestamp (b) (4) , an operator's facial gowning was observed making direct contact with equipment on the RABS line.
4. During multiple interventions, the RABS (b) (4) was (b) (4) into a Grade B environment and a (b) (4) operator, gowned to Grade B standards, performed a sanitization procedure on a (b) (4) (b) (4) which was (b) (4) the Grade B zone. This procedure, which involves wiping a sterilized (b) (4) with (b) (4) , removes the (b) (4) validated sterile state, rendering it only sanitized. This sanitization was further compromised when the operator's forearm and hand passed directly over the (b) (4) , obstructing first air. This was observed during:
   a. OI-18 (Machine Breakdown for Minor Repairs) at timestamp (b) (4)
   b. OI-20 (Performing Cleaning with (b) (4) Wipes at Filling Station) at timestamp (b) (4)
   c. OI-22 (Machine Breakdown and Repairs Intervened by Engineering Crew) at timestamp (b) (4)

E. Your airflow visualization studies and media fills fail to represent actual commercial manufacturing conditions. For example:

1. During Video OI-10 Running of Filling Machine at Minimum Speed, the capping bowl and chute that feeds the (b) (4) unit has a (b) (4) covering over it. The same (b) (4) covering is shown over the capping bowl and chute in Video OI-11 Running of Filling Machine at Maximum Speed.

SEE REVERSE OF THIS PAGE	Lisa L. Flores, Investigator Rafeeq A. Habeeb, Investigator	LLF RAH	April, 17th 2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483responses@fda.hhs.gov	April 7th -17th, 2026 FEI NUMBER 3004086192

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Shankar R Mohole, General Manager Production	
FIRM NAME USV Private Limited	STREET ADDRESS H-13, 16, 16A, 17, 18, 19, 20, 21 & E-22, OIDC, Mahatma Gandhi Udyog Nagar Road
CITY, STATE, ZIP CODE, COUNTRY Dabhel, Daman, Daman And Diu, 396210 India	TYPE ESTABLISHMENT INSPECTED Sterile (b) (4) Drug Manufacturer

2. The table below shows the time periods during which the maximum number of operators were present in the filling room during media fill runs:

Media Fill	Date	Start Time	End Time	Duration
(b) (4)	June 18, 2024	(b) (4)	(b) (4)	2 minutes
	October 13, 2024			4 minutes
	July 21, 2025			11 minutes
	October 19, 2025			11 minutes

In contrast, during routine production operations of (b) (4) Injection (b) (4) mcg/mL, Batches (b) (4) manufactured on Tuesday, April 7, 2026, Thursday, April 9, 2026, and Thursday, April 16, 2026 respectively, a total of (b) (4) operators were observed in the vial filling and sealing room for periods ranging from 28 minutes to over 60 minutes. The absence of an entry/exit log for this room makes it impossible to determine the number of operators present at any given time without direct physical observation.

OBSERVATION 4

Control procedures are not established which monitor the output and validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically, your visual inspection process for sterile products is inadequate:

A. Your firm manufactures sterile injectable products including (b) (4) (b) (4) Injection. Review of your visual inspection procedures, statistical evaluation protocols, and trending reports revealed the following deficiencies:
Specific Findings

SEE REVERSE OF THIS PAGE	Lisa L. Flores, Investigator Rafeeq A. Habeeb, Investigator	LLF RAH	April, 17th 2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483responses@fda.hhs.gov	April 7th -17th, 2026
	FEI NUMBER 3004086192

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Shankar R Mohole, General Manager Production	
FIRM NAME USV Private Limited	STREET ADDRESS H-13, 16, 16A, 17, 18, 19, 20, 21 & E-22, OIDC, Mahatma Gandhi Udyog Nagar Road
CITY, STATE, ZIP CODE, COUNTRY Dabhel, Daman, Daman And Diu, 396210 India	TYPE ESTABLISHMENT INSPECTED Sterile (b) (4) Drug Manufacturer

1. No Action Limits Established -Your statistical evaluation protocols calculate only alert limits using Mean (b) (4) Standard Deviations. No action limits are established for any critical defect type.
2. No alert or action limits established for:
   Black particles:
   - No limits established for (b) (4) (all strengths: (b) (4) mcg/mL)
     Limits established only for (b) (4) mg(b) (4) mL

   Glass particles:
   - No limits established for (b) (4) mg(b) (4) mL
     Limits established only for (b) (4) mcg/mL

   Broken vials:
   - No limits established for any product

   Cracked vials:
   - No limits established for any product

   Fibers (when tracked separately from particles):
   - No limits established for any product
     Fibers are combined with particles as "particle/fiber" in trending data, preventing separate monitoring and control

SEE REVERSE OF THIS PAGE	Lisa L. Flores, Investigator Rafeeq A. Habeeb, Investigator	LLF RAH	April, 17th 2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483responses@fda.hhs.gov	April 7th -17th, 2026
	FEI NUMBER 3004086192

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Shankar R Mohole, General Manager Production	
FIRM NAME USV Private Limited	STREET ADDRESS H-13, 16, 16A, 17, 18, 19, 20, 21 & E-22, OIDC, Mahatma Gandhi Udyog Nagar Road
CITY, STATE, ZIP CODE, COUNTRY Dabhel, Daman, Daman And Diu, 396210 India	TYPE ESTABLISHMENT INSPECTED Sterile (b) (4) Drug Manufacturer

SOP DMF-SOP-0350 Section 5.8.11 classifies these as "Critical defects" that "may cause serious adverse reactions or death of the patient if the product is used."

Your trending reports document occurrences of these defects:

- Broken/cracked vials: Documented in trending data but no limits established
- Fibers: Detected in multiple batches but no separate limits when not combined with particles

Although an alert limit of (b) (4) vials is established for glass particles in (b) (4) mcg/mL, Batch (b) (4) mcg/mL, US product, manufactured February 2023) contained (b) (4) glass particles—double the alert limit—yet no investigation was performed.

3. Inadequate Particle Characterization Procedures - Your procedures do not require characterization of particles and fibers to determine whether they are extrinsic (contamination) or intrinsic (process-inherent) unless an alert limit is exceeded. Your current procedure states that extrinsic particulates indicating filth, sterility assurance issues, or cGMP violations are unacceptable even if statistical sampling criteria are met. However, without characterization, you cannot determine if particles are extrinsic.

   For defect types without established alert limits (glass particles, fibers when tracked separately, broken/cracked vials), no investigation is triggered and particles are never characterized. This means batches may be released containing uncharacterized particles of unknown origin and unknown patient safety risk, and you cannot apply your own batch disposition criteria requiring identification of extrinsic particulates.

SEE REVERSE OF THIS PAGE	Lisa L. Flores, Investigator Rafeeq A. Habeeb, Investigator	LLF RAH	April, 17th 2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483responses@fda.hhs.gov	April 7th -17th, 2026
	FEI NUMBER 3004086192

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Shankar R Mohole, General Manager Production	
FIRM NAME USV Private Limited	STREET ADDRESS H-13, 16, 16A, 17, 18, 19, 20, 21 & E-22, OIDC, Mahatma Gandhi Udyog Nagar Road
CITY, STATE, ZIP CODE, COUNTRY Dabhel, Daman, Daman And Diu, 396210 India	TYPE ESTABLISHMENT INSPECTED Sterile (b) (4) Drug Manufacturer

B. For (b) (4) products packaged in (b) (4) bottles, including (b) (4) (b) (4) your visual inspection process does not include adequate destructive testing methods to ensure product quality. Your current procedure only allows for external visual inspection of (b) (4) containers, which cannot detect:

1. Particulate matter suspended in the product solution.
2. Contamination, discoloration, or phase separation of the product.
3. Foreign matter or defects that may be present inside the container but not visible through (b) (4) packaging materials.

Although your firm initiated destructive testing on (b) (4) (b) (4) this practice has not been adequately implemented or validated. Specifically:

1. Lack of Operator Training: Personnel performing destructive testing have not received formal training on the procedure, acceptance criteria, or defect recognition.
2. Absence of Training Materials: No defect kit or reference standards have been established to train operators on identifying unacceptable product attributes during visual inspection.
3. No Written Procedure: There is no documented procedure describing how to properly prepare or transfer the (b) (4) solution from the (b) (4) container to the test tube used for visual inspection, creating risk of contamination or sample integrity issues.

All batches of (b) (4) packaged in (b) (4) containers were manufactured and released for U.S. distribution without adequate destructive visual inspection. Examples include but are not limited to: (b) (4) (b) (4)

SEE REVERSE OF THIS PAGE	Lisa L. Flores, Investigator Rafeeq A. Habeeb, Investigator	LLF RAH	April, 17th 2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483responses@fda.hhs.gov	April 7th -17th, 2026
	FEI NUMBER 3004086192

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Shankar R Mohole, General Manager Production	
FIRM NAME USV Private Limited	STREET ADDRESS H-13, 16, 16A, 17, 18, 19, 20, 21 & E-22, OIDC, Mahatma Gandhi Udyog Nagar Road
CITY, STATE, ZIP CODE, COUNTRY Dabhel, Daman, Daman And Diu, 396210 India	TYPE ESTABLISHMENT INSPECTED Sterile (b) (4) Drug Manufacturer

C. Your visual inspection qualification kits (b) (4) do not include particle size characterization data for any of the defect standards. The kit certificates identify defects only by type (e.g., 'Particle,' 'Fiber,' 'Glass Particle') without specifying particle dimensions. Without this characterization, your firm cannot verify that:

- threshold-sized particles (b) (4) µm for spherical particles, (b) (4) µm for fibers) are included in the kits
- operators can reliably detect particles in the reject zone (≥(b) (4)% PoD), or
- the inspection method meets required detection sensitivity

D. On April 16, 2026, (b) (4) visual inspections of (b) (4) mL vials in routine production were observed. The total inspection times, including (b) (4), ranged from (b) (4) of (b) (4) containers. Accounting for approximately (b) (4), the actual time spent examining containers (b) (4) ranged from (b) (4) This equates to (b) (4) All observations were below the USP <790> requirement of 5 seconds per container against each background (10 seconds total per container).

In addition, the firm's procedure allows inspectors to (b) (4) The firm has not validated that the reduced per-container time in their procedure or in actual visual inspections provides equivalent defect detection.

SEE REVERSE OF THIS PAGE	Lisa L. Flores, Investigator Rafeeq A. Habeeb, Investigator	LLF RAH	April, 17th 2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483responses@fda.hhs.gov	April 7th -17th, 2026
	FEI NUMBER 3004086192

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Shankar R Mohole, General Manager Production	
FIRM NAME USV Private Limited	STREET ADDRESS H-13, 16, 16A, 17, 18, 19, 20, 21 & E-22, OIDC, Mahatma Gandhi Udyog Nagar Road
CITY, STATE, ZIP CODE, COUNTRY Dabhel, Daman, Daman And Diu, 396210 India	TYPE ESTABLISHMENT INSPECTED Sterile (b) (4) Drug Manufacturer

E. Your visual inspector qualification records are inadequate to verify compliance with USP <790> timing requirements. Qualification records for visual inspectors do not document start time, end time, or total duration of the qualification sessions. Review of the firm's logbook showed inspectors took an average (b) (4) to inspect (b) (4) containers during their (b) (4) qualifications, providing only (b) (4) per container total (b) (4) (b) (4)

OBSERVATION 5

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written, or followed.
Specifically, personnel monitoring procedures for aseptic operations are inadequate. The finger dabbing method consisting of touching the plate with four fingers together instead of rolling each finger separately was observed on the following occasions:

A. April 9, 2026: During the setup for sterile filling operations for (b) (4) Injection (b) (4) mcg, Batch (b) (4), operators rolled four fingers together as a group and the thumb separately, rather than rolling each finger individually across the (b) (4) plate surface. This technique does not ensure adequate surface area contact and sample collection from each individual finger.

B. April 14, 2026: During the filling of (b) (4) on the (b) (4) line for protocol DMF/MSP/26/016 "Protocol for filling of (b) (4) in (b) (4) mL (b) (4) Bottle in (b) (4) Bottle)",

SEE REVERSE OF THIS PAGE	Lisa L. Flores, Investigator Rafeeq A. Habeeb, Investigator	LLF RAH	April, 17th 2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483responses@fda.hhs.gov	April 7th -17th, 2026
	FEI NUMBER 3004086192
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Shankar R Mohole, General Manager Production	
FIRM NAME USV Private Limited	STREET ADDRESS H-13, 16, 16A, 17, 18, 19, 20, 21 & E-22, OIDC, Mahatma Gandhi Udyog Nagar Road
CITY, STATE, ZIP CODE, COUNTRY Dabhel, Daman, Daman And Diu, 396210 India	TYPE ESTABLISHMENT INSPECTED Sterile (b) (4) Drug Manufacturer

operators continued to demonstrate the same inadequate finger dabbing technique observed on April 9, 2026.

Without proper contact between each finger and the media plate, accurate results cannot be obtained to detect microbial contamination on operators (b) (4)

OBSERVATION 6

Written procedures for qualifying, controlling, and evaluating suppliers and materials used in aseptic processing areas are not established, written or followed.

Specifically, your firm lacks a comprehensive, risk-based program for qualifying and monitoring suppliers of critical consumables used in ISO 5 (Grade A) areas, including garments, (b) (4), wipes, and disinfectants. Your firm relies solely on supplier Certificates of Analysis without performing independent verification testing for sterility, lacks particle shedding evaluations for cleanroom garments and wipes, and has not conducted supplier audits or established a qualification and requalification program. For example, sterile gowns from (b) (4) were accepted without independent sterility testing, and sterile (b) (4) from (b) (4) were tested using statistically unjustified single-unit sampling, despite direct contact with surfaces in aseptic processing areas.

OBSERVATION 7

Each component is not tested for conformity with all written specifications for purity, strength, and quality.

SEE REVERSE OF THIS PAGE	Lisa L. Flores, Investigator Rafeeq A. Habeeb, Investigator	LLF RAH	April, 17th 2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483responses@fda.hhs.gov	April 7th -17th. 2026 FEI NUMBER 3004086192
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Shankar R Mohole, General Manager Production	
FIRM NAME	STREET ADDRESS
USV Private Limited	H-13, 16, 16A, 17, 18, 19, 20, 21 & E-22, OIDC, Mahatma Gandhi Udyog Nagar Road
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Dabhel, Daman, Daman And Diu, 396210 India	Sterile (b) (4) Drug Manufacturer

Specifically, your firm lacks appropriate testing of components used in the manufacture of your drug product. For example, your firm lacks a specific identity test to detect (b) (4) in all shipments, containers, and lots of (b) (4) before use in the manufacturing of (b) (4) Tablets. In the last two years your firm has manufactured over (b) (4) batches of (b) (4) Tablets for distribution into the US market including but not limited to: batches (b) (4) (b) (4) The product has an expiration date of (b) (4)

OBSERVATION 8

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's investigation into the out-of-specification (b) (4) results for (b) (4) (b) (4) Tablets, USP (b) (4) mg (Batch (b) (4) OOS DEV-08261) is inadequate because it fails to provide sufficient scientific justification for the proposed change from (b) (4) sampling (b) (4) mg) to (b) (4) sampling (b) (4) mg) and does not correlate (b) (4) (b) (4) results with (b) (4) dosage unit (b) (4) . Your investigation concludes that the (b) (4) sampling plan is "susceptible to variations in sample (b) (4) resulting in variability of the amount of collected (b) (4) sample and impacting the (b) (4) result" due to "(b) (4) " in this (b) (4) (b) (4) however, your firm did not explain why this sampling plan was acceptable for (b) (4) previously manufactured and released batches between 2023-2025, nor does it provide data demonstrating that these released batches exhibited acceptable (b) (4) in the (b) (4) dosage units despite allegedly inadequate (b) (4) sampling. Furthermore, the firm proposes that

SEE REVERSE OF THIS PAGE	Lisa L. Flores, Investigator Rafeeq A. Habeeb, Investigator	LLF RAH	April, 17th 2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483responses@fda.hhs.gov	April 7th -17th, 2026
	FEI NUMBER 3004086192

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Shankar R Mohole, General Manager Production	
FIRM NAME USV Private Limited	STREET ADDRESS H-13, 16, 16A, 17, 18, 19, 20, 21 & E-22, OIDC, Mahatma Gandhi Udyog Nagar Road
CITY, STATE, ZIP CODE, COUNTRY Dabhel, Daman, Daman And Diu, 396210 India	TYPE ESTABLISHMENT INSPECTED Sterile (b) (4) Drug Manufacturer

larger sample sizes (b) (4) minimum (b) (4) mg) are necessary to achieve representative (b) (4) (b) (4) results, yet each individual tablet contains only (b) (4) mg of (b) (4) significantly less than the minimum (b) (4) sampling size (b) (4) mg). Your firm failed to explain how the (b) (4) process, which utilizes an even smaller (b) (4) per unit (b) (4) mg) than the allegedly inadequate (b) (4) sampling (b) (4), can consistently produce tablets with acceptable (b) (4) if the (b) (4) does exhibitthe degree of (b) (4) claimed in the investigation.

OBSERVATION 9

Laboratory records do not include complete data derived from all tests, examinations, and assay necessary to assure compliance with established specifications and standards.

Specifically,

Your analysts have been given permission within the Empower software to view numerical results in the review window, allowing them to see area counts of peaks while changing the processing methods, without requiring the chromatograms to be saved. Using this method your firm have tested over (b) (4) batches of finished drug products for assay by HPLC in the last two years.

Using this method your firm has tested over (b) (4) batches of finished drug products for assay by HPLC in the last two years including but not limited to (b) (4) (b) (4)

SEE REVERSE OF THIS PAGE	Lisa L. Flores, Investigator Rafeeq A. Habeeb, Investigator	Lisa L. Flores -S Digitally signed by Lisa L. Flores -S Date: 2026.04.17 11:44:42 +05'30' RAFEEQ HABEEB -S Digitally signed by RAFEEQ HABEEB -S Date: 2026.04.17 11:41:57 +05'30'	April, 17th 2026