DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483Response@fda.hhs.gov	11/10/2025-11/21/2025* FEI NUMBER 3009876430

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Sunil S. Karpe, Site Head

FIRM NAME	STREET ADDRESS
Shilpa Medicare Limited	Plot No. S-20 to S-26, Pharmaceutical Formulation SEZ, TSIIC, Green Industrial Park
CITY, STATE, ZIP CODE, COUNTRY Polepally, Jadcherla, Telangana, 509301, India	TYPE ESTABLISHMENT INSPECTED Drug Product 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 did not include adequate validation of the aseptic and sterilization process.

Specifically,

A. Your firm's qualification of airflow in critical areas is insufficient to evaluate unidirectional airflow, contamination risk, and aseptic processing line suitability due to the smoke studies being performed using a (b) (4) This smoke is not neutrally buoyant, potentially masking the true airflow pattern and making it difficult to identify issues like recirculating air or dead spots.

Additionally, the following discrepancies were noted:

1. Turbulence
   - (b) (4) (Pushing of (b) (4) stoppers)
   - Addition of (b) (4) Stoppers)
   - Addition of (b) (4) Stoppers)
   - (Removal of fallen (b) (4) from track)
   - (Removal of fallen vials)
   - Removal of Fallen vials)
   - Machine setup)
   - (Removal of fallen vials)

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	JOSEPH A. PIECHOCKI JR -S Digitally signed by JOSEPH A. PIECHOCKI JR -S Date: 2025.11.21 07:19:30 -05'00' SANDRA A. BOYD -S Digitally signed by SANDRA A. BOYD -S Date: 2025.11.21 07:02:11 -05'00' YOU KEUN KIM -S Digitally signed by YOU KEUN KIM -S Date: 2025.11.21 07:01:09 -05'00'	Joseph A. Piechocki, Investigator Sandra A. Boyd, Investigator Youkeun Kim, Investigator	11/21/2025

- (b) (4) (Removal of unstoppered vials from track during (b) (4) loading)
- (Removal of filled vial from track during (b) (4) loading)
- (b) (4) (Removal of fallen vials during (b) (4) loading)
- (b) (4) (Adjustment of (b)(4))

2. Not all activities are represented during the smoke studies:
   a. The equipment (b) (4) was removed prior to execution of the smoke studies demonstrating setup activities performed on (b)(4). This (b) (4) is located (b) (4) the filling line. Removal of this (b) (4) results in the setup of filling equipment smoke studies not being representative of routine production. The removal of the equipment (b) (4) is not mentioned in associated protocol or report.
   b. The smoke studies videos for (b) (4) do not include the dissemination of the sterile equipment (b)(4) bags to their use locations and the placement of forceps and scissors throughout the (b) (4)
   c. Not all environmental monitoring activities are demonstrated. The following locations were not executed during the smoke studies:

(b) (4)

- Microbial monitoring by settle plate: (b) (4) locations)
- Microbial monitoring by air sampling: (b) (4) locations)

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- Pushing of (b) (4) stopper (b) (4) from the chute with the help of forceps during filling activity by (b) (4) station (b) (4) location)
- Removal of (b) (4) stopper/vial from (b) (4) by stoppering station and by filling station (b) (4) locations)
- Removal of (b) (4) non-viable particle counter isokinetic probes caps near (b) (4) filling station, stoppering station, (b) (4) capping station, (b) (4) loading/unloading (b) (4) (b) (4) (b) (4) locations)
- Transfer of empty (b) (4) from filling (b) (4) station (b) (4) to (b) (4) from filling station (b) (4) location)
- Removal of (b) (4) vials and transfer of (b) (4) to loading/unloading (b) (4) storage cabinet (b) (4) location)

(b) (4)

- Microbial monitoring by settle plate: (b) (4) locations)
- Microbial monitoring by air sampling: (b) (4) locations)
- Removal of (b) (4) non-viable particle counter isokinetic probes caps near filling station, (b) (4)

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(b) (4) locations)

d. Fallen vial interventions are grouped together by common intervention names although they are performed in different locations. The following are fallen vial interventions which were not performed during the smoke studies:

(b) (4)

- Removal of fallen empty vial from filling (b) (4) station
- Removal of fallen, broken or jammed filled vials from filling track by filling station (b) (4) using (b) (4) from the (b) (4) of the (b) (4) (b) (4)
- Removal of fallen vials during (b) (4) loading by (b) (4) loading (b) (4) station and (b) (4) loading (b) (4) of (b) (4)
- Removal of filled vial from track during (b) (4) loading by (b) (4) loading (b) (4) station and (b) (4) loading (b) (4) of (b) (4)

(b) (4)

- Removal of fallen empty vials at (b) (4) with the help of forceps using (b) (4) from the (b) (4) of the (b) (4)
- Removal of fallen filled vials from filling track – by filling station (b) (4) using (b) (4) from (b) (4) of (b) (4)

e. On 13Nov2025, we (SAB, JAP, and YK) observed an operator performing the addition of (b) (4) stoppers with numerous (b) (4) stopper bags sitting next to the (b) (4) stopper bowl during the manufacture of (b) (4) Injection - (b) (4) mg/vial, batch (b)(4) in (b)(4). The smoke study for this intervention is not performed with the additional stopper bags present.

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3. The amount of smoke is not adequate to evaluate activities in the following videos:
   - (b) (4) Addition of (b) (4) Stoppers)
   - (Removal of fallen (b) (4) from track)
   - (b) (4) (vial withdrawn)
   - (b) (4) (Removal of fallen vials)
   - (Removal of Fallen vials)
   - Machine setup)

4. The nozzles on the wand used to distribute smoke in the following smoke studies were observed pointing downwards. This is significant as by pointing the nozzles downwards, it is unclear whether the air flow pattern observed is due to the flow of the air in the area being evaluated or due to the velocity of the smoke leaving the wand.
   - (b) (4) (Sample taken from (b) (4) bottle)
   - Microbiological monitoring by Settle plate (Vial filling line (b) (4) loading and unloading (b) (4) & Vial sealing machine (b) (4)
   - (b) (4) Microbiological monitoring by Air sampling (Vial filling line (b) (4) loading and unloading (b) (4) & Vial sealing machine (b) (4)
   - (b) (4) Unloading (b) (4) Dynamic Condition
   - (b) (4) Pushing & Pulling of (b) (4) from (b) (4) loading - unloading conveyor with (b) (4) to (b) (4)
   - (b) (4) (Pushing of vial (b) (4) on (b) (4) loading-unloading conveyor (b) (4)

5. The angle of the following video recordings does not include the full range of air flow: for example, from the (b) (4) of the (b) (4) to the (b) (4)
   - (b) (4) (Addition of (b) (4) Stoppers)

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- (b) (4) (vial withdrawn) non-routine
- (b) (4) (Sample taken from (b) (4) bottle)

B. Your firm's written procedure for (b)(4) requalification does not include sufficient detail for consistent replication of worst-case challenge conditions during requalification, and the challenge testing practice fails to simulate actual use conditions.

1. Your firm's performance qualification protocol (Doc# SMLJ/QAD/SOP-GEN/F01-01) lacks specific biological indicator (BI) placement criteria. The protocol states only that BIs should be placed "inside (b) (4) bag containing (b) (4) tube" without specifying the exact worst-case location for (b) (4) (i.e. the geometric center inside the tube).

2. Your firm lacks written procedures for BI placement in challenging configurations. Operators place BIs inside (b) (4) tubes by (b) (4) but this practice is not documented. Additionally, (b) (4) introduces (b) (4) entry points not present during routine sterilization, invalidating the challenge test and failing to demonstrate sterilization efficacy under actual use conditions.

3. Your firm's load pattern documentation lacks adequate detail for article orientation. For example, the "Filling and (b)(4) Load (Maximum Load)" document (Doc# CPS(b) (4) 025) shows (b) (4) scissors in (b) (4) pouches but does not specify whether scissors should be loaded open or closed, which affects (b) (4) and sterilization efficacy.

C. The aseptic process simulation procedure states qualified personnel *"shall perform* (b) (4) *intervention during media fill"*. The Entry and Exit Procedures for Vial Filling Areas procedures states, *"Only authorized personnel (Trained, qualified and certified) are allowed to enter the Vial filling area. However, it is to ensure that personnel should participate in next routine media fill"*. There is no definition of activities to be performed by the operator to be trained, qualified

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or certified, and your procedures allow for personnel to participate in performing aseptic manipulations during the filling of commercial products prior to participating in a media fill. For example, Employee (b) (6) was hired on (b) (6) and participated in his first aseptic filling of (b) (4) mg/ml (b) (4) Injection Batch (b)(4) on (b) (4) He was documented as performing setup on (b) (4) Injection - (b) (4) mg/vial Batch (b)(4) on (b) (4) from (b)(4), and Batch (b)(4) on (b) (4) from (b)(4). Employee (b) (6) did not participate in a media fill (b)(4) until (b) (4)

In total, Employee (b) (6) participated in (b) (4) batches for (b) (4) different products (b) (4) prior to participating in a media fill.

D. The equipment qualifications conducted for the (b)(4) used during the manufacture of (b)(4) drug products, including (b) (4) Injection, do not ensure their adequate performance. For example, during the (b) (4) of (b) (4) (on Line (b) (4) the time between the (b) (4) and all (b) (4) varied between (b) (4) to (b)(4) depending on the (b) (4) Similarly, during the (b) (4) of (b)(4) (on Line (b) (4) the time between the (b) (4) and all (b) (4) varied between (b) (4) and (b)(4). The time for the (b) (4) was not included as an acceptance criterion, and the delay in all (b) (4) was not assessed to ensure that this does not have a negative impact on the (b) (4) and processes (including the (b) (4) times) for drug products. (b) (4) is considered critical for the (b) (4) used in the manufacture of (b) (4) Injection.

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E. The Validation of (b) (4) Sterilization for the (b) (4) for (b) (4) used in the manufacture of (b) (4) Injection (b) (4) mg/vial, approved 29 Oct. 2025 for (b)(4), and 28 Sep. 2024 for (b)(4), failed to demonstrate the that biological indicator (BI)/ chemical indicator (CI) placements represent the most challenging conditions for (b) (4)

1. No risk assessment could be provided to show the current BI/CI locations used during (b) (4) decontamination of the (b) (4) are worst case.

2. On 12 Nov 2025, we observed the (b) (4) decontamination cycle for (b)(4) vial (b) (4) (b) (4) At that time, we observed:
   a. The (b)(4) used on (b) (4) do not have (b) (4) to separate the (b) (4) during (b) (4) During (b) (4) we observed (b) (4) (b) (4). There is no assurance the (b) (4) reaches all areas of the (b) (4) The BI/CI indicators are not placed where the (b) (4) which can be used up to (b) (4) are never (b) (4)

   b. We observed equipment parts touching each other such as the (b) (4) hoses and (b)(4) bags. We also observed the (b) (4) sensor which later would be assembled on the (b) (4) tank, sitting on bottom surface of (b) (4) There is no assurance that these contacted surfaces would have successful (b) (4)

F. Media fills are not representative of routine production. As interventions are grouped together under a general description, the actual location where the intervention takes place is unknown. For example:

- For (b)(4), the 'Removal of fallen filled vials from filling track' could be performed using (b) (4) from the (b) (4) of the (b) (4) or 'Removal of fallen vials during (b) (4) loading could be performed by the (b) (4) station, the (b) (4) loading (b) (4) or by the (b) (4) station).
- For (b)(4), the 'Removal of fallen filled vials from filling track' could be located by the filling station (using (b) (4) from the (b) (4) of the (b) (4) or

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the stoppering station. 'Removal of fallen empty vials at (b) (4) with the help of forceps' can be performed using (b) (4) from the (b) (4) of the (b) (4) (b) (4)

OBSERVATION 2

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

Specifically,

A. The visual inspection program for sterile drugs, including (b) (4) Injection (b) (4) mg/vial, is deficient. For example:

1. The visual inspection kits and procedure used to qualify visual inspectors of sterile drug products, including (b) (4) Injection (b) (4) mg/vial, do not adequately qualify visual inspectors to detect defects:

   a. There is no justification for the selected defects that are placed within the visual inspection kits (including the selection and number of particle and fiber materials within the kits) and the exclusion of some defects from all kits (including (b) (4) (b) (4) defects for the (b) (4) mL (b) (4) vial kit, which is representative of the (b) (4) Injection (b) (4) mg/vial drug product).

   b. The number corresponding to the vial used for identifying good and defective vials is on the top of the vial with UV active ink. However, the number of each vial was easily identifiable under regular light, including for the (b) (4) mL (b) (4) vial and (b) (4) mL (b) (4) vial kits within the visual inspection booths.

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c. The selected defects within the kits are not randomized, as all (b) (4) kits have the defects within the (b) (4) numbered vials of the kit. In addition, at least (b) (4) specific defects (including glass particle, metal particle, plastic particle, black particle) are in the same order for at least (b) (4) defect kits. Furthermore, vials that were identified as good vials within the (b) (4) mL (b) (4) vial kit had cap defects which according to your personnel would have been rejected in a normal visual inspection.

d. The qualification of the visual inspectors does not require the visual inspector to document the defect identified during the qualification process. Instead, the qualifier will document on a checklist if the vial identified was a false positive, true positive, false negative, or true negative.

e. The initial qualification of visual inspectors requires the visual inspector to inspect each kit (total (b) (4) kits) (b) (4) times, for a total of (b) (4) inspections during qualification. The visual inspector is also re-qualified (b) (4) examining each drug product presentation and vial (b) (4) times. The kits are used for (b) (4) without changing the vial number of the defect. Furthermore, the qualification of the kit defects is performed by visual inspectors who are also re-qualified using the same defects.

2. The process for examining (b) (4) drug products for visible particles (b) (4) does not ensure that visible particle defects are detected. During the (b) (4) visual inspection of (b) (4) mg/mL (b) (4) Injection Batch (b) (4) on 17Nov2025, we (JAP and YK) observed (and 1 visual inspector subsequently confirmed) that one of the (b) (4) vials had an apparent white fiber, however both visual inspectors performing the inspection previously identified this vial as not having any particles or fibers. In addition, on 18Nov2025, (b) (4) additional samples were pulled for (b) (4) and we (JAP and YK) observed (and 2 visual inspectors subsequently confirmed) that two of the

additional (b) (4) vials had an apparent white fiber, however the visual inspectors previously identified these vials as not having any particles or fibers.

3. The following additional deficiencies were identified with the 100% visual inspection process:

   a. The library of defects or procedure does not include or describe all potential (b) (4) defects, including (b) (4) product between vial and stopper, does not describe the proper (b) (4) appearance of the (b) (4) Injection drug product, and does not provide instructions for verifying the (b) (4) within the vials by comparing the product (b) (4) within the vial to the reference as observed during the inspection.

   b. To date, particle, fiber, or foreign matter defects identified during visual inspection that are always categorized as major defects have not been characterized or identified as extrinsic and intrinsic.

   c. During the (b) (4) drug products for visible particles (b) (4) the (b) (4) location for each vial selected is not documented. In addition, during the visual inspection on 17Nov2025, the visual inspector did not inspect the (b) (4) tubes used during the (b) (4) however the visual inspector documented that this was performed.

   d. Light intensity of the visual inspection booths is determined (b) (4) However, during the inspection, we (JAP and YK) observed light intensities throughout the marked visual inspection areas that did not meet the light intensity acceptance criterion per procedure. Furthermore, visual inspectors were observed performing visual inspection activities in the areas where light intensities were observed outside

the limit. In addition, a (b) (4) eye break is taken (b) (4) where the visual inspection booth lights are turned off. The light intensities of the booths are not reverified once the break is completed and prior to resuming visual inspection activities.

B. Fallen vial interventions are grouped together by common interventions names although they are performed in different locations making it difficult to get meaningful information out of the tracking of interventions. Additionally, interventions which occur during commercial manufacturing are not tracked or trended per container size. Instead, interventions for all vial sizes (b) (4) mL to (b) (4) mL) are grouped together resulting in changes occurring within a specific container size not being detected.

OBSERVATION 3

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the equipment to produce aseptic conditions.
Specifically,

(b) (4) used in the manufacture of (b) (4) Injection, (b) (4) mg/vial, is not composed of smooth and cleanable surfaces. During review of the inside of the clean (b) (4) the following was observed:

A. (b) (4) contains (b) (4) drains throughout the inside of the (b) (4) for removal of the sprayed (b) (4) water used during cleaning. The inside of these drains are never cleaned or monitored for microbial growth.

B. The manufacturer of the (b) (4) is (b) (4) while manufacture of the filling machine is (b) (4) To integrate the (b) (4) machines, a caulk-like material was used inside the (b) (4) This material is not easily cleanable and appears to be flaking.

C. A rust-like substance by the (b) (4) and on forceps, chipping paint, hard to clean (b) (4) chipping/flaking of (b) (4) spots on the (b) (4) stickers, residue, (b) (4) caulking, and blue/black electrical tape was observed inside (b)(4).

D. A fiber was observed hanging from the (b) (4) frame in (b)(4) as well as chipped paint, gashes in (b) (4) dings/dents in the (b) (4) for stoppering, and difficult to clean (b) (4) residue was also observed on the (b) (4) near the (b) (4)

E. The (b) (4) installed (b) (4) the HEPA filters on (b)(4) were secured with (b) (4) tape. This tape was observed to be peeling throughout the (b) (4)

F. The (b) (4) on (b) (4) appeared to be missing (b) (4) parts in the area where (b) (4) stoppers transfer to stopper bowl.

G. The (b) (4) by the (b) (4) is positioned such that the (b) (4) is extended over the stopper bowl upon (b) (4) of (b) (4) This was observed during the addition of (b) (4) stoppers.

H. The NVP probes used inside the (b) (4) are not sanitized after removing the covers after (b) (4) potentially leading to recontamination of the area.

I. During the observation of cleaning activities performed on (b)(4) on 14Nov2025, the following was noted:

1. Production Supervisor documented "complies" for the dismantling of the stopper bowl, (b) (4) bowl, (b) (4) on the pre cleaning check list. This was noted at 11:38 am. At the time of his signature, the equipment was still assembled inside the (b) (4) and would not be removed until after (b)(4). The actual time the equipment

was dismantled was not documented. Additionally, the times and personnel involved in the breakdown and the personnel involved in cleaning of the (b) (4) was not documented.

2. After spraying the inside of the (b) (4) with (b)(4), the operators wipe down the equipment with a dry lint free cloth. While watching the drying of (b)(4), we observed the operator obtaining a stool so he could lean inside the (b) (4) to wipe the back wall.

J. There are no spray guns, used in the spraying of (b)(4) during cleaning, located on (b) (4) of the (b) (4) making it difficult to clean all equipment surfaces.

K. During the walk-through inspection of (b)(4) on 10 Nov. 2025, the spray gun hoses, used to clean the (b) (4) were observed to be discolored. Management could not provide any documentation for when the last time the hoses were changed. The (b)(4) cleaning procedure states, *"Spray gun, spray gun tube found damaged/leakage, color change, same shall be replaced with new one"*. This procedure is not being followed. While watching cleaning of (b)(4) on 14 Nov. 20205, (b) (4) of the hoses leaked, one due to cracking in several places due to brittleness.

L. Missing screws on the (b) (4) inside the (b) (4) SOP states to remove the screws to clean (b) (4) the (b) (4) inside the (b) (4) Not all the screw are replaced.

OBSERVATION 4

The separate or defined areas and control systems necessary to prevent contamination or mix-ups are deficient.

Specifically,

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483Response@fda.hhs.gov	11/10/2025-11/21/2025* FEI NUMBER 3009876430

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Sunil S. Karpe, Site Head

FIRM NAME	STREET ADDRESS
Shilpa Medicare Limited	Plot No. S-20 to S-26, Pharmaceutical Formulation SEZ, TSIIC, Green Industrial Park
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Polepally, Jadcherla, Telangana, 509301, India	Drug Product Manufacturer

A. Non-viable particle (NVP) monitoring counter locations, limits, and excursion handling are not scientifically justified. For example,

1. The location of NVP counters within Line (b) (4) are not placed in locations where routine activities are occurring (e.g. in the stopper addition and in-process (b) (4) (b) (4) areas) nor are there counters placed in areas where particles were generated during the study and no existing probe is present in the area (e.g. under the (b) (4) area at (b) (4) location (b) (4) in (b) (4)

2. Line (b) (4) excursions for (b) (4) µm particles require an impact assessment when an excursion of (b) (4) occurs; however, Line (b) (4) excursions for (b) (4) µm particles will require an impact assessment when (b) (4) of excursions occur. There is no scientific justification for the difference in how alarms are handled and when impact assessments should be initiated.

3. There is no impact assessment conducted nor are alarms always assessed when the specification limit for Class 100 areas is exceeded at any time during production. Alert and action alarms are established within the Grade A (Class 100) areas at >(b) (4) and >(b) (4) counts, respectively) for (b) (4) µm particles/ft^3. The specification limit for Class 100 areas is not more than (b) (4) µm particles/ft^3. However, during the manufacturing of (b) (4) Injection (b) (4) mg/vial Batch (b) (4) three (b) (4) µm particles/ft^3 excursions occurred within the (b) (4) area where particle counts were obtained at (b) (4) and (b) (4) µm particles/ft^3. Empty vials were present during these excursions, but no impact assessment was initiated nor any corrective actions documented.

B. Non-viable particle counter (NVPC) tube lengths in your (b) (4) exceed (b) (4) meter without evaluation of particle loss. During the IQ/OQs, only the length of the (b) (4) tubing, and not the height of the probe was considered in determining whether the distance from the isokinetic probe met the NMT (b) (4) m requirement. When recalculated, all distances between

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the isokinetic probes to the NVPC box exceeded the NMT (b) (4) m requirement. When recalculated:

(b) (4)

C. Your firm's Line (b) (4) (Equipment # SMLJ (b) (4) 051) has (b) (4) gasket where portion of the gasket was modified with sealant and (b) (4) tape. However, your firm could not provide a document to demonstrate what risk assessment was performed before the modification, and what appropriate qualification was done to ensure that the modification will not affect the quality or sterility of the drug production procedure. In addition, your firm could not provide documentation to show what kind of sealant was used (b) (4) to the Line (b) (4)

OBSERVATION 5

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,

A. During the manufacture of (b) (4) Injection (b) (4) mg/vial Batch (b)(4), 12 low (b) (4) (b) (4) alarms were identified within the (b) (4) loading/unloading conveyor. The impact assessment form completed for these excursions stated no impact on product quality as these (b) (4) (b) (4) alarms observed for fraction of seconds, all other parameters were within limit, and the process report was reviewed and found satisfactory. The impact assessment is deficient since at least 5 alarms were observed for over one minute (including an alarm up to 26 minutes), and there is no assessment for how the low (b) (4) may impact the (b) (4) within the (b) (4) In addition, root causes including (b) (4) variation and (b) (4) fluctuations

were documented. However, all potential root causes were not evaluated for each time excursion, as an assessment was only documented for 6 of the 12 alarms.

B. During the filling of (b) (4) Injection (b) (4) mg/vial Batch (b) (4) 39 non-viable particle excursions over (b) (4) locations (including at least 11 which are over the Class 100 specification limit of not more than (b) (4) µm particles/ft^3) were observed, which required an impact assessment to be initiated. The root causes identified for the alarms included (b) (4) movement within the (b) (4) fluctuations of stray light, and electronic noise due to turbulence in (b) (4) during filling and sealing. However, the root causes are not scientifically justified as historical data reviewed did not show this level of alarms, including during identified interventions or sealing activities. The impact assessment stated that there was no impact as the vials present were in stoppered condition. However, areas such as the (b) (4) are open vials (b) (4) Furthermore, the assessment was not conducted for the (b) (4) which contributed to 14 of the 39 alarms.

C. SML7-OOS-24-005 was initiated on 07May2024 due to an out of specification during the Related Substance by HPLC testing for the impurity (b) (4) in (b) (4) (b) (4) Injection (b) (4) mg/vial Batch (b) (4) The investigation concluded that the likely root cause was related to the two deviations (UP-(b) (4) -24-009 and UP(b) (4) -24-010) for less exposure of (b) (4) vials to the (b) (4) and an increase (b) (4) time during (b) (4) step that occurred during the manufacture of the batch. However, during additional samples were pulled as required by the deviations, which concluded this impurity was within the specification limit (stating there was no impact to product quality) and therefore does not support the identified root causes as related to the deviations. Although the batch was subsequently rejected, the root cause identified and subsequent corrective actions do not ensure that there is adequate control of this impurity formation during the manufacturing process to prevent recurrence.

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Sunil S. Karpe, Site Head	
FIRM NAME	STREET ADDRESS
Shilpa Medicare Limited	Plot No. S-20 to S-26, Pharmaceutical Formulation SEZ, TSIIC, Green Industrial Park
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D. SJ/OOS/25/001 was initiated on 14May2025 due to an out of specification for the assay of the (b) (4) for (b)(4) Tablets (b) (4) mg & (b) (4) mg Batch (b) (4) %, with specification of (b) (4) % to (b) (4) %). The investigation concluded that the root cause was related to collecting a (b) (4) sample of the (b) (4) instead of a (b) (4) sample (b) (4) (b) (4) The subsequent (b) (4) sampling produced a passing assay result. However, there was no assessment of the (b)(4) for this batch, as the (b) (4) sampling may be concealing the ultimate root cause for the (b) (4) nor was there sufficient scientific to support that the results from the original sample were invalid.

E. During the observation of cleaning activities performed on (b)(4) on 14 Nov. 2025, we observed the Production Supervisor documenting "complies" for the dismantling of the stopper bowl, (b) (4) bowl, (b) (4) chute and (b) (4) on the pre cleaning check list even though this activity had not yet been performed. Management confirmed this equipment cannot be removed during the pre cleaning check list as the equipment first needs to be cleaned (b) (4) to remove any traces of the (b) (4) drug they previously filled. The practice of documenting the removal of this equipment during pre cleaning even though the equipment is not removed is standard practice for the supervisors working on (b)(4).

Although this data integrity discrepancy became known during this inspection, no investigation was initiated to determine the scope of this discrepancy or if other documents are being falsified due to inaccurate forms.

F. (b) (4) Injection (b) (4) mg/vial batch record states "(b) (4) ". Changeover Operation and Cleaning of Vial Filling & Stoppering Machine states (b) (4)

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(b) (4) """. Scientific data could not be provided for exceeding (b) (4)

Whether this (b) (4) is maintained on (b) (4) is unknown as the (b) (4) bottle is not monitored. (b)(4) monitors the (b) (4) bottle but no action is taken when the (b) (4) exceeds (b) (4) For example, (b) (4) Injection – (b) (4) mg/vial reached a (b) (4) of (b) (4) No justification for setting the "(b) (4) *alarm*" for the (b) (4) bottle on (b)(4) at (b)(4).

G. Deviations are not initiated for critical alarms, interventions exceeding media fill limits, leak testing for (b) (4) and NVP excursions. Instead, impact assessments are performed and filed with individual batches. These impact assessments are not tracked or trended and do not include a thorough root cause evaluation or corrective actions. The following number of impact assessment forms were issued in 2024 and 2025:

Form name	Form number	# issued in 2024	# issued in 2025
Impact Assessment Sheet for Interventions exceeding Maximum Allowable Limit/Longest Duration Allowed/Maximum Persons Allowed to Perform the Intervention	(b) (4) SOP-GEN/089/F07	83	48
Evaluation Report of NVPC Excursion	(b) (4) SOP-OPC/025/F02	48	54
Evaluation Report of NVPC Excursion	(b) (4) SOP-OPC/052/F02	146	145
(b) (4) Leak Test Failure Impact Assessment Form	(b) (4) SOP-GEN/079/F07	0	4
Impact Assessment of Critical Alarms	(b) (4) SOP-GEN/081/F04	96	295
Totals		519	691

*The date of issuance could not be determined for 49 impact assessment forms and therefore were not included in the table above.

In addition, impact assessment documents are issued manually (logbooks containing a specified number of forms) and electronically (individual forms). Logbooks are issued with indexes to document where forms are used and upon use, the individual forms are removed from the log and filed with the corresponding batch record. Since the last FDA inspection, 6 impact assessment logbooks were issued without an index resulting in not tracking the usage of 208 critical alarm forms.

OBSERVATION 6

Equipment and utensils are not cleaned and maintained at appropriate intervals to prevent malfunctions and contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

A. Equipment used in the manufacture of drug products are not adequately maintained and cleaned. For example, during the walkthrough of the facility on 10Nov2025, we (JAP, YK) observed the following:

1. Inspection of (b) (4) SMLJ (b) (4) 120 equipment noted apparent (b) (4) residue observed on the interior of the (b) (4) near the (b) (4) duct. Swab sampling of the (b) (4) duct of (b) (4) surface of the (b) (4) bowl yielded results for (b)(4) of (b)(4) ppm and (b)(4) ppm, respectively, which is outside the acceptance criteria of not more than (b)(4) ppm. This equipment was documented as clean following the validation (b) (4) cleaning cycle after processing for (b) (4) Capsule (b) (4) mg Batch (b)(4).

2. Inspection of the (b) (4) SMLJ (b) (4) 141 equipment noted an apparent (b) (4) residue observed on the (b) (4) apparent (b) (4) remaining on the (b) (4) duct exterior, and an apparent (b) (4) leak from the (b) (4) duct. This equipment was documented as clean following (b) (4) Tablets (b) (4) mg Batch (b) (4)

3. Inspection of the (b) (4) Machine SMLJ (b) (4) 003 in (b)(4) identified the (b) (4) attachment connecting the (b) (4) to the (b) (4) equipment with apparent (b) (4) tape located within the product pathway. According to your production personnel, this was added by the operations staff to improve the seal between the (b) (4) and the (b) (4) attachment. However, there was no procedural requirement nor documentation provided to support the use of this material for the (b) (4) attachment.

B. The cleaning program for the validation of equipment cleaning is deficient. For example:

1. Rinse samples are collected from the (b) (4) rinse for analytical evaluation during cleaning validation. However, the total volume of the rinse where the sample is obtained is not documented to ensure the maximum allowable carryover is adequately calculated.

2. The swab locations chosen for cleaning validation are not scientifically justified or adequately assessed. For example, the swab locations for the (b) (4) SMLJ (b) (4) 120 on Line (b) (4) did not consider locations such as the (b) (4) or (b) (4) in its assessment nor are there studies performed which support the selection of the difficult to clean areas.

C. Magnehelic gauges for differential pressures within the Grade A manufacturing area are not continuously monitored to ensure proper function. During the manufacture of (b)(4) Injection (b) (4) mg/vial Batch (b) (4) I (JAP) observed at least (b) (4) magnehelic gauges showing differential pressures below the specified limits of (b) (4) Pa, including values reading (b) (4) Pa. Differential pressures are not continuously monitored, as these pressures are only required to be monitored at the (b) (4) of the batch. These differential pressure readings were not identified by production personnel during the manufacturing, and the differential pressure values were recorded (b) (4) after the magnehelic gauges were fixed, without documenting the differential pressure readings at the time of the incident.

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Sunil S. Karpe, Site Head

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Polepally, Jadcherla, Telangana, 509301, India	Drug Product Manufacturer

OBSERVATION 7

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications and test procedures designed to assure that components and drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

A. Your firm failed to provide complete method equivalency study comparing your in-house analytical test method to the compendial method for detecting (b)(4) in (b)(4). Your firm only provided an interim report of (b)(4) testing in (b)(4) (Doc# SML7(b)(4)AMV/REPORT/0017-00). The interim report was generated by your contracting laboratory who does product release test. The interim report only documents failure to perform the compendial method; No comparative data or statistical analysis between your in-house method and the compendial method was provided to demonstrate equivalency or non-inferiority.

B. Your firm's method equivalency report failed to demonstrate statistical equivalency or non-inferiority of your inhouse test method to the compendial method. For example:
   1. In Analytical Method Equivalency Report of Assay Method for (b)(4) Tablet (b)(4) mg by HPLC (Doc# AFD/MES(b)(4)/AS/004R(b)(4) your firm performed assays using both in house method and the compendial method and calculated relative standard deviation (RSD) for each method's data. Your firm then inappropriately combined results from both methods to calculate an overall RSD value. Calculating RSD values is a measure of precision, not a statistical test for method comparison. Your firm did not conduct any statistical testing to demonstrate that your in-house method performs equivalently to or better than the compendial method.

   2. In Analytical Method Equivalency Report for Assay by HPLC test of (b)(4) Capsule (b)(4) mg and (b)(4) mg (Doc# SMLJ/QCD/REP-MIS/0012-00), your firm performed

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assays using both in house method and the compendial method and obtained assay results. But your firm did not conduct any statistical testing to demonstrate that your in-house method performs equivalently to or better than the compendial method. In addition, you used different testing parameter for compendial method due to the equipment limitation without any scientific justifications to support the parameter adjustment.

C. Your firm's method validation transfer method failed to include scientific acceptance criteria. Your firm performed analytical method transfer validation for Related Substance Method (b) (4) of (b) (4) Injection (b) (4) mg/vial by HPLC from Unit (b) (4) to Unit (b) (4) (Doc# SMLJ/AMT (b) (4) SML/R (b) (4) The acceptance criteria were states as "% impurity results obtained at receiving laboratory should be comparable with the originating laboratory result." There were no scientific, quantitative acceptance criteria to demonstrate that the receiving laboratory can perform the test method as same as originating laboratory.

D. The sample size of (b) (4) ml for (b) (4) used during microbial examination of (b) (4) (b) (4) is not appropriate to derive a statistically valid number of colonies. Review of the (b) (4) block (b) (4) microbial results from (b) (4) showed that out of (b) (4) samples taken during this time, (b) (4) % of the samples resulted in less than (b) (4) CFUs (resulting in (b) (4) CFU (b) (4) ml). (b) (4) from (b) (4) block is used during cleaning and formulation of non-sterile (b) (4) products.

OBSERVATION 8

The written stability program for drug products does not include reliable, meaningful, and specific test methods.

Specifically,

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Sunil S. Karpe, Site Head

FIRM NAME	STREET ADDRESS
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A. Your firm failed to include all relevant test results and data in the report. Your firm's Analytical Method Validation Report of Related Substance for [(b) (4)] Injection [(b) (4)] mg/vial (Doc# AFD/AMV [(b) (4)] FP/RS/098R [(b) (4)] includes forced degradation test. Your firm performed acid-stress tests and obtained two results within the expected degradation level, yet only the data with the highest mass balance result was reported on the report without any justification.

B. Your firm failed to ensure that your contracting laboratory, which is responsible for product release testing, maintained analytical methods in compliance with updated procedures and specifications. Your contracting laboratory (Shilpa Medicare Limited Unit VII) revised their standard operating procedure for Analytical Method Validation/Verification (Doc# SML7 [(b) (4)] SOP/0026-05) to include new specifications for forced degradation testing. However, neither your contracting laboratory nor your firm conducted retrospective reviews of existing analytical methods to ensure continued compliance with the updated specifications for following:

- Analytical Method Validation Report of Related Substance for [(b) (4)] Injection [(b) (4)] mg/vial (Doc# AFD/AMV [(b) (4)] FP/RS/098R [(b) (4)]
- Analytical Method Validation Report of Related Substance for [(b) (4)] Tablets [(b)(4)] mg & [(b) (4)] mg (Doc# AFD/AMV/ [(b) (4)] FP/RS/099R [(b) (4)]

***DATES OF INSPECTION**
11/10/2025(Mon), 11/11/2025 (Tue), 11/12/2025 (Wed), 11/13/2025 (Thu), 11/14/2025 (Fri), 11/15/2025(Mon), 11/16/2025 (Tue), 11/17/2025 (Wed), 11/18/2025 (Thu), 11/19/2025 (Fri)

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