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	1/15/2024-1/19/2024
	FEI NUMBER 3014129013

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Uday Chile, Director

FIRM NAME	STREET ADDRESS
Brassica Pharma Pvt Ltd	Plot No. T-68, T 68 (Pt), T-63, Midc, Tarapur, Boisar
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Thane, Maharashtra, 401502 India	Sterile 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

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

Microbiologists responsible for performing sterility testing and collecting environmental monitoring, personnel monitoring, and (b) (4) samples confirmed they do not collect, test, and incubate all samples. For samples that are not collected or tested, a result is still recorded in the reported laboratory records to indicate the sample was collected, incubated, and had a result that was within limits.

1. Inspection of the incubators in the microbiology laboratory on January 15, 2024, identified sterility tests, personnel monitoring, environmental monitoring, and (b) (4) samples that were supposed to have been collected and under incubation, but were not present. Associated logbooks and analytical worksheets containing testing data were incomplete. Examples included:

   a. Records identified ongoing sterility tests for (b) (4) batches (b) (4) (b) (4) (US batches), (b) (4) batch (b) (4) (US batch), (b) (4) batch (b) (4) batches (b) (4) There were no (b) (4) samples in the 20-25°C incubator or (b) (4) samples in the 30-35°C incubator for any of these ongoing tests.

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The analyst responsible for performing the sterility test confirmed the tests were never performed. Records were fabricated to document the tests were performed and the records documented (b) (4) checks signed by two analysts, documenting no growth, for samples that did not exist.

There were samples in the incubator for (b) (4) batches (b) (4) (b) (4) but no records had been made for testing these batches.

b. There were no personnel monitoring samples in the incubators. Procedure MI/009 "Environment Monitoring" requires personnel monitoring for all personnel exiting the aseptic area. There were 73 documented entries/exits in the aseptic entry/exit log from January 10-January 15, 2024, that should have had associated samples under incubation. A microbiologist confirmed none of the samples were collected.

Additionally, from November 5, 2023 – December 30, 2023, there were no entries into the personnel monitoring logbook to indicate any samples had been collected.

c. There were no (b) (4) air samples in the incubators. Procedure MI/009 "Environment Monitoring" requires (b) (4) monitoring of the production area from (b) (4) Grade A locations and (b) (4) Grade B locations. A microbiologist confirmed the samples for January 10-14, 2024, were not collected.

d. There were no (b) (4) surface monitoring contact plates in the incubator. (b) (4) contact plates for surface monitoring are supposed to be taken (b) (4) from (b) (4) Grade A locations and (b) (4) Grade B locations. A microbiologist confirmed the samples for January 10-14, 2024, were not collected.

e. Not all settle plates were present in the incubator. Procedure MI/009 "Environment Monitoring" requires settle plates be taken for [redacted] periods [redacted] during filling.

There were no settle plates present in the incubator from January 14, 2024, when [redacted] batches [redacted] were filled. There should have been [redacted] sets of settle plates for this day.

There was one set of settle plates with an unknown exposure time from January 13, 2024, when [redacted] batches [redacted] were filled. There should have been [redacted] sets of settle plates for this day.

There was one set of settle plates with an unknown exposure time from January 11, 2024, when [redacted] batches [redacted] were filled. There should have been [redacted] sets of settle plates for this day.

There was only one set of settle plates with an unknown exposure time from January 10, 2024, when [redacted] batches [redacted] were filled. The set was missing plates from Grade A sample point [redacted] There should have been [redacted] sets of settle plates for this day.

f. Samples for [redacted] were documented to be under incubation for samples collected January 10, 11, 13, and 14, 2024. None were

present in the incubator. A microbiologist confirmed the samples were not collected.

2. A microbiologist responsible for sterility testing, collecting environmental monitoring, and collecting personnel monitoring confirmed samples were routinely not collected and tested for batches manufactured during 2023. Sterility test room biometric access records, aseptic entry/exit log, and HR records showed personnel documented to perform testing were not actually present. For example:

   a. Biometric access records showed the analyst responsible for sterility testing of (b) (4) batches (b) (4) did not enter the testing room on October 14, 2023, when the batches were documented to have been tested. These batches were released to the US market.

      The entry and exit log for the aseptic area and HR Records showed personnel responsible for (b) (4) air sampling, settle plates, contact plates, and personnel monitoring samples associated with batches (b) (4) were not present when samples were documented to have been collected.

   b. Biometric access records showed the analyst responsible for sterility testing of incoming empty tube lots (b) (4) did not enter the sterility testing room on August 4, 2024, the date of testing. These lots were used in the filling of US market batches (b) (4)

   c. Biometric access records showed the analyst responsible for sterility testing of (b) (4) (b) (4) batches (b) (4)

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[redacted] (b) (4) was not present in the sterility testing room on the days the samples were documented to have been tested. These batches were released to the European market.

3. Grade A settle plate (b) (4) collected on January 13, 2024, was reported by the analyst to have (b) (4) CFU during plate reading. When the plate was inspected prior to the end of incubation it was observed to have (b) (4) CFU, an action level result.

Prior to the inspection, no sterility failures have ever been reported and no alert or action level findings have ever been reported for environmental monitoring, personnel monitoring, or (b) (4) samples. For samples that were inspected while under incubation during this inspection, failing results were observed:

1. Lot (b) (4) of (b) (4) (US market) was failing its sterility test on January 19, 2024.

2. Lots [redacted] (b) (4) of (b) (4) (domestic market) were failing their sterility test on January 19, 2024.

3. For environmental monitoring samples under incubation during the inspection that were collected between January 10-18, 2024, there were approximately 37 Grade A action level excursions, 17 Grade B action level excursions, and 2 Grade B alert level excursions.

OBSERVATION 2

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

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1. Your firm aseptically fills the OTC finished drug products, (b) (4) Ointment for the US market. Your sterilization process includes holding the ointment base, at (b) (4) equipment ID BR2/PR/EQ/MR-001, located in the (b) (4) Room of your facility's manufacturing block. In your performance qualification (PQ) protocol (P/PR/PR004-02) for this sterilization step, and associated report R/PQ/PR004, you challenge the sterilization process by (b) (4) (b) (4) The sterilization process is conducted followed by sterility testing of (b) (4) taken from the tank after the sterilization cycle has completed. (b) (4) (b) (4) You failed to demonstrate that this sterilizing process is effective under worst case conditions by using any biological indicators in your qualification study. You also failed to demonstrate how (b) (4) sample taken for testing is representative of the entire batch, (b) (4) size.

2. Following the sterilization process, your firm (b) (4) located in an adjacent room. The aseptic connection that's done to connect the transfer piping from the (b) (4) equipment ID BR2/PR/EQ/MR-001, located in the (b) (4) Room" to the manufacturing tank (PLM) ID: BP2/PR/EQ/PLM-001, is performed under Grade C environmental conditions.

3. Your firm performs aseptic filling on Lines (b) (4) On Jan. 15th and 16th we observed filling on Line (b) (4) This filling line has minimal barrier protection in the area that houses the (b) (4) and where open sterile tubes pass by on the line prior to being filled. A high concentration of operator activity was observed in this area on both days. Your media fill study (Protocol P/MR/PR001-10 and Report R/MF/PR001-10) conducted for these filling lines was not

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representative of your commercial manufacturing process in terms of size and processing length. Your standard commercial batch size for the U.S. marketed sterile drug products, packaged in (b) (4) g tubes, is (b) (4) tubes; however, your media fill study consisted of only (b) (4) g, tubes.

4. Your firm's Aseptic Process Simulation (Media Fill), outlined in procedure SOP PR/017, Protocol P/MR/PR001-10 and Report R/MF/PR001-10, dated October 22, 2023, failed to include interventions representing worst-case production activities during commercial manufacturing. Numerous interventions were observed in production, which were not captured at all or in sufficient number in the Media Fill, to represent the observed manufacturing conditions.

   The following are examples of different interventions and/or incidences observed in the commercial batch production on Jan. 15th and 16th, during aseptic filling of the sterile product, (b) (4) Gel (b) (4) %), (b) (4) g tube, Batch # (b) (4) (Jan 15) and # (b) (4) (Jan. 16), which were not represented in the Media Fill Study:

   a. On Jan. 15th, operators were observed removing the empty (b) (4) that hold the sterile unfilled tubes from the filling line and exchanging it with a full (b) (4) of sterile, empty, ointment tubes. This exchange, which involves an operator walking across the room close to the aseptic filling line and the exposed (b) (4) was observed greater than 6 times in less than a (b) (4) time interval during filling.

      Per SOP PR/017, and Protocol P/MF/PR001-10, this activity is to be performed only (b) (4) times during a media fill study.

   b. Loading the (b) (4) with empty tubes to be placed on the filling line. This was observed on Jan. 15th greater than 6 times between (b) (4) and on Jan. 16th from the start of filling at approximately (b) (4) (operator lunch break).

Per SOP PR/017, and Protocol P/MF/PR001-10, this activity is to be performed only (b) (4) times during a media fill study.

c. An operator was observed removing an unfilled sterile tube from the filling line and placing it into a (b) (4) being loaded with empty sterile tubes where it will go back into machine to be filled.

This is not included in the interventions listed in SOP PR/017 and there is no documentation of it being performed in any media fill.

d. The line was stopped, and an operator was observed on Jan. 15th, (b) (4) of the filling line near the (b) (4) station and performing an adjustment to the machine.

This (b) (4) intervention is not found on the list of interventions in SOP PR/017, and/or Protocol P/MF/PR001-10, nor was any documentation found in the media fill to show this was simulated.

e. Operator (b) (6) was observed on Jan. 16th, standing on a stool, and reaching over the filling machine to (b) (4) on the (b) (4) which holds the sterile bulk drug product. His torso and arms were directly over the uncovered area of the filling line while there were open sterile unfilled tubes on the line below. This activity was observed more than 6 times during the filling process on Jan. 16th.

This intervention was not found in media fill SOP PR/017, and/or Protocol P/MF/PR001-10 or anywhere in the media fill batch records.

5. Per your media fill protocol P/MF/PR001-10, Step (b)(4) tubes are analyzed based on the change of (b)(4) indicator (b)(4) Your analysts are not instructed, and your protocol does not instruct analysts to inspect the sample for (b)(4)

6. Meaningful airflow pattern studies were not performed for the aseptic processing lines. The studies did not include evaluation of any set-up activities or interventions.

7. There are (b)(4) mechanical parts (accessories) on the filling line, the (b)(4) (b)(4) that have direct contact with the inside of the sterile ointment tubes prior to being filled with the sterile drug product. Additionally, a (b)(4) ointment tube barrier contacts the open end of the sterile tubes on the filling line.

   Per the Production Manager, and Sr. Production Manager, the (b)(4) ointment tube barrier are not sterilized.

8. The US market (b)(4) ointment products are packaged in (b)(4) containers. There has been no evaluation to determine whether the formulation is appropriate to prevent proliferation of microorganisms that may be introduced (b)(4)

OBSERVATION 3

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

On Jan. 15th and 16th, 2024, while observing set-up, filling, and transfer of equipment and components on Filling Line (b)(4) (equipment ID BP2/PR/EQ/WIF001), for the aseptically filled finished drug product (b)(4) Gel, (b)(4) %), (b)(4) gram tube, Batch (b)(4) (Jan. 15th) and Batch (b)(4) (Jan. 16th), poor aseptic processing behavior was observed. This filling line is used to

manufacture US market product. Examples of the observed poor aseptic behavior include:

1. On both Jan. 15th and 16th, during loading of the [redacted] box) that holds the sterile ointment tubes used during filling, machine operators were observed directly touching the inside surface of the sterile tubes with their hands. These tubes are primary packaging for the aseptically filled sterile drug product. Procedure SOP PR/070, "Interventions During Tube Filling", requires the use of forceps to handle sterile ointment tubes, but the procedure was not followed.

2. The [redacted] used to hold the sterile ointment tubes on the filling machine does not undergo [redacted] sterilization. Per your firm, this [redacted] is wiped down with [redacted] prior to the start of filling. [redacted] On Jan. 15th, I observed these [redacted] being handled by the operators during filling (loading, moving the loaded [redacted] and empty [redacted] for reload) without ever observing them being wiped down with [redacted] The operator's hands were observed inside the [redacted] while removing it from the filling machine and carrying it across the room to refill. The operators were in direct contact with the same inside surfaces of the [redacted] that come in direct contact with the sterile unfilled ointment tubes.

3. On Jan. 16th, during line set-up and placement of the [redacted] an operator was observed leaning their entire torso, forearms, and head into the area of the filling machine [redacted] where aseptic filling of sterile ointment into sterile tubes takes place.

4. During filling on Jan.16th we observed exposed skin on the bridge of an operator's nose between the nose bridge on the goggles and hood/face covering as well as on the side of their cheek and

on their forehead. These operators were working in the aseptic filling area performing interventions near the (b) (4) where open sterile tubes pass prior to filling.

5. Operators were observed reaching their hands and forearms over the open product (b) (4) during set-up for aseptically filled (b) (4) batch (b) (4)

6. There is no (b) (4) on the product (b) (4) As a result, an operator must manually check the (b) (4) while product is being added to the (b) (4) During these checks, the operator was observed with their hands, arms, and head leaning over open tubes and the product (b) (4) during aseptic filling of (b) (4) batch (b) (4)

7. Operators were observed kneeling on the ground and placing their hand and forearm on the ground during set-up for (b) (4) batch (b) (4) on January 16, 2024. The operators did not change any gowning or gloves before continuing set-up and aseptic filling.

OBSERVATION 4

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

1. Appropriate pressure differentials are not maintained between the Grade A filling area for filling line (b) (4) and the adjacent Grade D (b) (4) zone (b) (4) There is an (b) (4) between these areas where filled tubes are (b) (4) When the (b) (4) between the Grade B area of the line (b) (4) filling room and the Grade B corridor are (b) (4) the pressure differential between the Grade A and Grade D (b) (4) zone dropped to zero and (b) (4) were observed to push from the Grade D area into the Grade A area. The same pressure differential drop was observed when the (b) (4) zone (b) (4) was (b) (4) to the packing area.

2. On January 15, 2024, the (b) (4) barrier (b) (4) of the (b) (4) on Line (b) (4) and the (b) (4) equipment were not installed during aseptic filling of (b) (4) batch (b) (4). There was no documentation that had been made at the time of when the (b) (4) were removed, why they were removed, or whether it was acceptable to manufacture without them in place. The smoke studies filmed on October 3, 2023, and on April 19, 2023, also showed the (b) (4) were not present at the time.

OBSERVATION 5

Protective apparel is not worn as necessary to protect drug products from contamination.

1. SOP PR/009, entitled, "Cleaning and Sterilization of Garments", under "Inspection of washed garments", states, "If any part of the set is found to be stained or not in intact condition, discard the whole set corresponding to that serial number". It also states under "Destruction of garments", "Destroy the garments by cutting with scissors after completion of (b) (4) sterilization cycles or (b) (4)

   On January 15, 2024, operators working in the grade A area, during aseptic filling of (b) (4) (b) (4) Gel, (b) (4) %), (b) (4) gram tube, Batch (b) (4) were observed to have numerous stains and tears in their donned garments. Closer inspection of the garments once doffed by the operators revealed the following:

   a. (b) (4) stains were observed over most of the boots, suite and head coverings.

   b. Boots were observed to have numerous holes in them.

   c. Hoods were observed to have tears around the sides.

2. The number of sterilizations and wash cycles and the age of the garments was not being

monitored.

3. The goggles used in the aseptic filling areas have direct vents along the top of the goggles.

OBSERVATION 6

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

1. Non-viable particle counts are not collected in the Grade A filling area during filling operations. Samples are only collected before and after filling. However, the raw data, including the counts, are not recorded per the production manager.

   On Jan.15th, the filling machine [redacted] (b) (4) gears were directly exposed to the filling line. These gears and [redacted] (b) (4) move in rapid succession, which could result in generation of non-viable particles. This mechanical section of the machine was not covered or isolated in a way to protect the product.

2. No risk assessment has been performed to identify appropriate and specific locations for environmental monitoring samples. For example, on aseptic filling line [redacted] (b) (4) surface monitoring plate is taken for [redacted] (b) (4) batch from the Grade A filling area. The location is not specified, documented, and is chosen by the sampler at random.

OBSERVATION 7

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

1. Test method MI/010 "Sterility Testing of Empty Tubes, Finished Product and Raw Material as

per IP/BP/USP" has not been shown to be effective for testing US market products for sterility:

a. The method was not validated using the formulation for (b) (4) Ointment (b) (4) Ointment.

b. During sterility testing for (b) (4) batch (b) (4) and (b) (4) batch (b) (4) on January 18, 2024, the product did not fully dissolve prior to (b) (4) (b) (4) The test method does not describe (b) (4) but the analyst (b) (4) the samples for approximately (b) (4) before attempting (b) (4)

The product did not appear to readily (b) (4) As a result, the analyst loosened the manifold, potentially allowing product to bypass the (b) (4) Additionally, during testing of (b) (4) the analyst did not place the (b) (4) on the manifold.

c. The method validation for (b) (4) Ointment (b) (4) Ointment did not document the use or amount of (b) (4) to dissolve the product.

d. There was a lack of justification for only using approximately (b) (4) g of ointment from (b) (4) sample tube.

2. The microbial media used for environmental monitoring (settle plates, (b) (4) air samples, surface monitoring, and personnel monitoring) does not contain (b) (4) On January 16, 2024, during the set-up of (b) (4) batch (b) (4) an operator was observed spraying (b) (4) above and in the direction of a Grade A settle plate.

3. There is no microbial identification from environmental monitoring, personnel monitoring, or (b) (4) monitoring to evaluate the microbial flora of the aseptic manufacturing facility.

OBSERVATION 8

Written production and process control procedures are not followed in the execution of production and process control functions and documented at the time of performance.

1. Paper entry logs for the aseptic entry and exit area are not accurate, complete, and documented contemporaneously. An analyst responsible for environmental monitoring confirmed his name and signature had been written in the aseptic entry/exit logs to show he was present on days when he was not at the facility by an unidentified person. In other instances, the analyst stated he signed that he was present to complete the log based on the batches being manufactured, not because he had actually been present at that time. There were no aseptic entry/exit logs for March 10 - June 1, 2023, or July 7 - September 1, 2023.

   In addition to the paper entry/exit log, the aseptic area has a biometric entry and exit system that stores the previous (b) (4) entry and exit records. After the data was requested to be reviewed during the inspection on January 17, 2024, all data was deleted before it could be reviewed. The General Manager acknowledged the data had been deleted. This limited the ability to perform the inspection.

2. Equipment usage logbook for the Bulk Storage Vessel, (ID BP2/PR/EQ/ST-001), for the 2023 year was missing records from January 2023 and March 1-December 31, 2023.

3. Equipment usage logbook (2023) for the Manufacturing Tank (ID BP2/PR/EQ/PLM-001), is missing records from November 1-December 31, 2023.

OBSERVATION 9

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

Your manufacturing equipment cleaning validation studies failed to assess the effectiveness of your cleaning procedures to reduce the residual API to acceptable levels when your shared equipment is in the worst-case dirty conditions. Per your Protocol/Report, No. PR/CV/002-00, entitled, "Cleaning Validation Protocol/Report for Product: (b) (4) Ointment (b) (4) effective 07/28/2017, cleaning was performed after (b) (4) commercial scale batch manufactured (b) (4) batch), for (b) (4) batches (b) (4) cleaning).

Your cleaning instructions outlined in the following procedures allow for (b) (4) batches of the same product to be manufactured before any cleaning (type (b) (4) is initiated:

- PR/054, entitled, (b) (4) of Bulk Storage Vessel (ID BP2/PR/EQ/ST-001)"
- PR/056, entitled, (b) (4) of PLM (ID BP2/PR/EQ/PLM-001)"

For example, the following manufacturing equipment usage logs show (b) (4) batches of (b) (4) Ointment (b) (4) being manufactured prior to initiating cleaning:

(b) (4)

OBSERVATION 10

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Batch production and control records do not include complete information relating to the production and control of each batch.

1. Your firm does not record interventions during routine batch manufacturing. On January 15th and 16th, 2024, the following interventions were observed during the aseptic filling of (b) (4) (b) (4) Gel (b) (4) %), (b) (4) g tube, Batch # (b) (4) and Batch # (b) (4)

   a. Removal of the empty (b) (4) that supply the tubes to the filling line and exchanging it with a full (b) (4) of sterile ointment tubes.

   b. Removal of an unfilled sterile tube from the filling line.

   c. (b) (4) of the filling line near the (b) (4) station and performing an adjustment to the machine.

   d. Manual adjustment of the unfilled tubes prior to their entering the filling line.

   e. (b) (4) of the (b) (4) that holds the sterile bulk drug product.

2. Your firm does not record the filling line speed when filling sterile products.

3. Your firm does not record when the filling line is stopped, and the length of time it is stopped for, in the batch manufacturing record.

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Additionally, your firm's Sr. Production Manager, (b) (6) Production Manager (b) (6) and (b) (6) your Assistant QA Manager confirmed that they do not document routine interventions in the BMR or onto any other document that is associated with the BMR.

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Investigator
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