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 ORAPHARMInternational483responses@fda.hhs.gov	02/10/2025-02/21/2025 FEI NUMBER 3003821988

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mr. Jai Ashokan Velusamy, Chief Operations and R&D Officer

FIRM NAME	STREET ADDRESS
Somerset Therapeutics Private Limited	54/1 Budihal Village Nelamangala
CITY, STATE, ZIP CODE, COUNTRY	**TYPE ESTABLISHMENT INSPECTED**
Bengaluru, Karnataka, 562123, 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

There is a failure to submit a field alert report (FAR) to FDA within 3 working days of receiving information concerning bacteriological contamination in the distributed drug product. Specifically,

No FAR was submitted regarding bacteriological contamination observed in the aseptic process simulation (APS) Batch #(b) (4) . On 25 Sep 2024, APS Batch # (b) (4) was conducted on the (b) (4) filling line. On 30 Sept 2024, positive growth was observed in multiple filled units. Deviation investigation IR/DR/PD/24/049 was initiated on 30 Sep 2024 and closed on 09 Dec 2024. From 29 May 2024 (last successful APS) to 25 Sep 2024, (b) (4) batches of aseptically filled (b) (4) Injection USP and (b) (4) batches of (b) (4) Injection were manufactured on the (b) (4) filling line. In addition, (b) (4) batches of (b) (4) sterilized drug products were manufactured. These batches are currently in the U.S. market and within expiry.

OBSERVATION 2

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,

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SEE REVERSE OF THIS PAGE	Eileen A. Liu Joseph A. Piechocki	**Eileen A. Liu, Investigator (Lead)** **Joseph A. Piechocki, Investigator**	02/21/2025

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A. Deviation investigation IR/DR/PD/24/049 into contaminated APS units is inadequate in that it did not include scientifically supported conclusions. On 25 Sep 2024, you conducted an APS in Batch # (b) (4) on the (b) (4) filling line. On 30 Sep 2024 before incubation, you found units contaminated with *Bacillus cereus* group in multiple (b) (4) Your investigation identified that a nick in the (b) (4) tank (b) (4) tubing in combination with operator (b) (6) aseptic behavior being the root cause for the APS failure. However, your investigation lacked scientifically supported conclusion that an ingress of *Bacillus cereus* group through the nicked tubing definitely occurred. Also, you failed to identify in the APS video footage exactly when operator (b) (6) deficient aseptic behavior that contributed to the failure took place. From 29 May 2024 (last successful APS) to 25 Sep 2024, a total of (b) (4) batches of aseptically filled injectables and (b) (4) batches of (b) (4) sterilized injectables were manufactured on the (b) (4) filling line. These batches are currently in the U.S. market and within expiry. Your investigation is inadequate in that it lacked definitive root case and it failed to address all potentially compromised drug product lots currently in the U.S. market accordingly.

B. Investigations IR/LI/24/197-FD and IR/LI/24/383-AL were initiated due to an out of specification for individual unspecified impurity of (b) (4) Injection, USP Process Validation Batches (b) (4) (b) (4)%) and (b) (4) %) (specification limit NMT (b) (4) %) and for (b) (4) Solution, USP (b) (4) % Batch (b) (4) accelerated 3 month stability (b) (4) %, specification limit NMT (b) (4) % and (b) (4) %, specification NMT (b) (4) %). The impurity was subsequently identified as (b) (4) for (b) (4) Injection, USP. The root cause was determined to be related to the specific drug substance lot exhibiting a different impurity profile during the drug product shelf life compared to the exhibit batches. The root cause is deficient as there was no definitive root cause for the formation of the impurity. In addition, the CAPA included updating the specification limit for the injectable products, requiring pre-shipment samples for assessment by R&D, and not applying reduced testing, retesting, and skip lot testing procedures. The CAPA plan is inadequate as it does not address the root cause of the impurity profile for the drug substance and the impurity formation, and there was no establishment of a robust quality control strategy to ensure that incoming lots of drug substance can ultimately achieve drug product meeting its established quality attributes. Since the investigation, two process validation batches of (b) (4) Injection, USP

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and two process validation batches of (b) (4) Solution, USP have been released to the US market.

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,

The airflow visualization partial studies (smoke studies) performed on the (b) (4) and (b) (4) filling lines show the following deficiencies. The above filling lines are used to manufacture products for the U.S. market.

A. I (EL) watched video of smoke study of the (b) (4) filling line (b) (4) LAF for (b) (4) stoppers transfer performed on 13 Nov 2023. I (EL) noted ingress of Grade B air into the Grade A (b) (4) during transfer. I also observed the operator's deficient aseptic technique of quick movement during transfer created disruption to the unidirectional airflow.

B. I (EL) watched video of the dynamic smoke studies of the (b) (4) and (b) (4) filling line interventions performed on 04 Apr 2024. I (EL) noted the studies were not conducted under dynamic conditions. Although various interventions were performed, the (b) (4) RABS filling lines remained static and did not simulate the commercial manufacturing conditions.

OBSERVATION 4

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

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A. On 11 Feb 2025, we watched the aseptic filling of U.S. product (b) (4) Injection, USP (b) (4) mg/mL (b) (4) mL), Batch #(b) (4) (b) (4) vials) on the (b) (4) filling line. The following deficiencies were noted.

i. Items were not always adequately sanitized prior to transfer to the Grade A filling line. We observed an operator placed a bag containing sterile stoppers flat on its side on a cart. This operator proceeded to sanitize the top side of the bag using (b) (4) He turned the bag over to sanitize the bottom side. However, the just sanitized top side was now touching the cart surface that was exposed to the unsanitized bottom side of the bag. This bag was later transferred to the Grade A (b) (4) for (b) (4) of stoppers.

ii. After transferring the stopper bag inside the Grade A (b) (4) we observed the operator picking up a pair of scissors from a holder containing (b) (4) mL of (b) (4) This operator did not allow the scissors to dry before cutting the bag open. Tools or gloves sanitized using (b) (4) should allow to dry before aseptic handling.

iii. We observed the operator held the stopper bag directly over the (b) (4) blocking the unidirectional airflow to the (b) (4) while (b) (4) sterile stoppers. This aseptic operator's activity obstructed the path of unidirectional airflow (first air) to the sterile stoppers.

B. On 12 Feb 2025, I (EL) watched the aseptic filling of U.S. product (b) (4) Solution (b) (4) % (b) (4) mL), Batch #(b) (4) on the (b) (4) filling line. The following deficiencies were noted.

i. An operator was observed leaving the (b) (4) to the Grade A (b) (4) while sanitizing two bags of sterile bottles. It took this operator about (b) (4) to wipe each bag. During the

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approximate(b) (4) the (b) (4) to the Grade A (b) (4) (b) (4) to the (b) (4) RABS should kept (b) (4) when not in use to assure integrity of the Grade A condition.

ii. An operator was observed reaching into the (b) (4) sterile bag of the (b) (4) bagged primary packaging components (i.e., sterile bottles, (b) (4) or caps) without first sanitizing his hands. Operators should sanitize hands before handling items going into Grade A filling zone.

iii. The Grade A equipment surfaces that come in contact with the sterile primary packaging components are not always sterile. During dispensing, I observed sterile (b) (4) bottles, (b) (4) or caps having direct contact with equipment surfaces such as the non-sterile (only sanitized) loading (b) (4) It is unclear how sterile bottles, (b) (4) or caps maintain sterility if they touch non-sterile (only sanitized) equipment surfaces.

iv. I observed operators using the same side of a wipe up to 3 times to clean the Grade A side of the (b) (4) RABS (b) (4) before (b) (4) The appropriate technique of using the clean side of a wipe each time to apply parallel unidirectional and overlapping strokes was not observed by the cleanroom operators.

OBSERVATION 5

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions. Specifically,

On 11 Feb 2025, during the aseptic filling of U.S. product (b) (4) Injection, USP (b) (4) mg/mL (b) (4) mL), Batch #(b) (4) on the (b) (4) filling line. The following were noted.

A. Investigator Piechocki noted materials came off loose along the (b) (4) frames in the (b) (4) RABS Grade A filling room ceiling. You confirmed they are tapes used to additionally secure the (b) (4) to its frames. These tapes are approximately 2 cm in width and 135.5 cm in length. They were observed

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partially detached from the (b) (4) frames above the (b) (4) the (b) (4) exit, and the filling (b) (4) locations where open vials are situated during active filling. Management stated they were unaware of the loose tapes and did not know how long they have been in such condition.

B. On 18 Feb 2025 during the current inspection, you provided videos of static smoke study of the (b) (4) filling line impacted by the loose tapes. The following were observed. No adequate explanation was given by the firm.

i. In the (b) (4) Exit video, what appeared to an updraft of smoke can be seen along the loose tape from 00:14 to 00:16, 00:48 to 00:49, 00:55 to 00:56, and 01:06 to 01:07 time period.

ii. In the Filling (b) (4) video, what appeared to be an updraft of smoke can be seen along the loose tape from 00:00 to 00:04 and from 00:12 to 00:25.

OBSERVATION 6

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

You conduct (b) (4) for all (b) (4) filling lines Grade B areas to control microbiological contamination. All (b) (4) filling lines are used to manufacture drug products for the U.S. market. However, your (b) (4) efficacy study is inadequate in that the biological indicator (BI) and chemical indicator (CI) locations were not justified. No risk assessment was performed to determine appropriate indicator locations. Instead of placing them in most difficult to reach places, BIs and CIs were placed in the open areas of the Grade B cleanrooms during validation.

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OBSERVATION 7

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

Your viable environmental monitoring (EM) results are not always reliable because the (b) (4) (b) (4) plates incubation condition at (b) (4)(b) (4) °C is not supported by the growth promotion test (GPT). For example, section 4.10.2 of SOP QCB-091, entitled "Environmental Monitoring Programme for (b) (4) Line (b) (4) requires to incubate all EM (b) (4) plates at (b) (4)(b) (4) °C for NLT (b) (4) followed by (b) (4)(b) (4) °C for NLT (b) (4) However, during GPT the (b) (4) plates are only incubated at (b) (4)(b) (4) °C for ≤ (b) (4) You do not have growth promotion data to demonstrate the capability of (b) (4) media to support microorganism growth at (b) (4)(b) (4) °C.

OBSERVATION 8

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

A. There is no assurance that all active air sample data obtained using (b) (4) air samplers are reviewed and complete as part of the batch production record. Active air samples are obtained throughout the filling area within the filling line (fixed equipment) and the filling area (portable equipment) following QCB-050, "Environmental Monitoring Programme" and QCB-091, "Environmental Monitoring Programme for (b) (4) Line (b) (4). However, upon review of the electronic data associated with (b) (4) of the (b) (4) air samplers, 17 aborted runs were observed, including air samples collected within the (b) (4) areas and corridors. According to your microbiology personnel, these aborted runs are associated with samples which were collected, however the person collecting these samples did not visually ensure that the air sample was completed for the entire (b) (4) collection time, and these electronic data logs are not reviewed as part of the batch record.

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B. In-process (b) (4) are performed and documented by production and IPQA personnel at set intervals, as defined within the respective batch records. However, the Filling Line (b) (4) are equipped with (b) (4) which are not required to be used during filling. In addition, the (b) (4) reports included as part of the batch record were reviewed for (b) (4) Injection USP (b) (4) mg/mL (b) (4) mL) Batch (b) (4) Injection USP (b) (4) g/(b) (4) mL ((b) (4) mg/mL) Batches (b) (4) (Exhibit Batch for (b) (4) and (b) (4) Injection USP (b) (4) Units/(b) (4) mL (b) (4) Units/mL) and Batch (b) (4) (Exhibit Batch for (b) (4) However, (b) (4) obtained by the (b) (4) during the filling process were found to be out of the (b) (4) limits. There was no investigation initiated for these (b) (4) and there is also no procedural requirement to ensure these (b) (4) are used and the data associated are reviewed.

C. Filling Line (b) (4) is equipped with various detect functions, including "Safety (b) (4) det" (for detection of filling line (b) (4)), and "Grating detection" (for use of the gloves near the filling zone). However, there is no procedural or automated control to ensure that the correct detect functions are used and the data collected during the filling of a batch is complete. In addition, Filling Line (b) (4) is equipped with alarms, including (b) (4) alarms. These alarms are not captured or reviewed as part of the batch report.

OBSERVATION 9

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. (b) (4) drug substance used for the manufacture of (b) (4) (b) (4) Injection, USP (b) (4) is tested for related compounds following method RM-1100478-LC-RC. According to version 00 of the method used to release drug substance batches

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(b) (4) the quantitation limit for process impurity (b) (4) is (b) (4)%. The certificates of analysis for lots (b) (4) report the impurity as below quantitation limit (BQL) and (b) (4)%, respectively. However, there was no determination of the relative response factor (RRF) for this compound as part of method validation. In addition, the RRF was determined during the inspection as (b) (4). The updated analytical results obtained applying the appropriate RRF are (b) (4)% (resulting in reporting) and (b) (4)%, respectively. The current method and specification for the drug substance removed the requirement to report the (b) (4) impurity and does not require reporting for the drug product.

B. The method for related compounds for (b) (4) Injection, USP (b) (4) was validated as documented in MVR-FP-(b) (4)12-LC-RC-01. However, during the initial validation conducted following protocol MVP-FP-(b) (4)12-LC-RC-00, it was observed that the % recovery for determining the quantitation limit of unknown using (b) (4) did not meet the acceptance criteria due to degradation of the sample after (b) (4) as investigated under LI/22/133. The current method validation for determination of quantitation limit of unknown occurred within approximately (b) (4) but the sample solution stability for quantitation of known impurities was documented for (b) (4) at room temperature. The degradation of (b) (4) for unknown quantitation limit determination was not challenged in the current method validation to ensure that this degradation did not occur, and therefore further justify the sample solution stability of (b) (4) to adequately quantitate unknown impurities.

C. All known impurities identified within (b) (4) drug substance are not specified and adequately quantified. During the (b) (4) drug substance assay and related compounds method validation of test method RM-RASO0052-LC-AS & RC to support (b) (4) Injection, USP (b) (4) (b) (4) impurities were used for specificity and response factor determination, as these impurities were identified and supplied by your drug substance supplier. However, additional impurities have been detected within your testing and reported by your supplier which were not included in method validation as known impurities and therefore not included in specificity and response factor determination for adequate quantitation. Furthermore, there is no assessment of the other impurities identified within the

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drug substance supplier's Certificates of Analysis and the ability of the drug substance and drug product release method to adequately detect and quantitate these impurities, when applicable.

D. The specification of (b) (4) drug substance used in the manufacture of (b) (4) Injection, USP (b) (4) includes loss on drying (LOD) determination, which is only performed at initial release. However, the drug substance can absorb moisture up to approximately (b) (4)% within (b) (4) Upon additional testing conducted August 2022 of the drug substance with Batch (b) (4) (QC211068) and (b) (4) (QC211069), which both were released with an initial LOD test result obtained of (b) (4)% and used in the manufacture of Exhibit batches (b) (4), and (b) (4) a LOD result of (b) (4)% and (b) (4)%, respectively, of each drug substance lot was obtained. The requalification and subsequent testing of the drug substance does not adequately ensure that those specifications which vary throughout the material's shelf life are included.

Furthermore, during the manufacture of (b) (4) Injection, USP, the quantity of drug substance needed for manufacturing is corrected using the value for assay on a dried basis and LOD. Prior to the manufacture of Exhibit Batch (b) (4) the drug substance used was retested in January 2024, obtaining an assay value on the dried basis of (b) (4) µg/mg. The LOD result used for the manufacture of batch (b) (4) was (b) (4)%, however a result of (b) (4)% was achieved upon LOD testing conducted in August 2022. Based on the calculation within the batch manufacturing record, this resulted in an (b) (4) of approximately (b) (4)% of drug substance to the batch.

OBSERVATION 10

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

A. Laboratory results within the LIMS system are not adequately verified to ensure that data obtained from the chromatography system are appropriately reported. For example, the total impurities related to

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stability testing of (b) (4) Injection, USP (b) (4) drug product Batches (b) (4) (18 month, Long Term, Inverted), (b) (4) (Expiry Month, Room Temperature, Inverted), (b) (4) (Expiry Month, Room Temperature, Upright), (b) (4) (Expiry Month, Room Temperature, Inverted), (b) (4) (12 month, Accelerated, Inverted), and (b) (4) (12 Month, Long Term, Upright) were reported within LIMS as (b) (4)%, (b) (4)%, (b) (4)%, (b) (4)%, (b) (4)%, and (b) (4)%, respectively. However, review of the data obtained in the Empower chromatography system did not adequately transfer all unknown impurities to the LIMS which were above the quantitation limit, and therefore the reported results should have been (b) (4)%, (b) (4)%, (b) (4)%, (b) (4)%, (b) (4)%, (b) (4)%, respectively.

B. The documentation related to the antimicrobial assay of (b) (4) drug substance and (b) (4) Injection, USP (b) (4)) is not complete. The assay testing requires the drug substance test sample and reference standards to be dried and cooled in a desiccator containing (b) (4) and maintaining at NMT (b) (4) % RH prior to further preparation as the material is highly hygroscopic and is therefore prepared on a dried basis. The test record documenting the execution of the assay does not include verification of desiccant and humidity as well as cooling times to ensure the sample was adequately dried following the procedure.

C. Laboratory records do not ensure that the correct glassware is used during standard and sample preparation. For example (b) (4) Injection, USP requires standards and samples to be prepared in (b) (4) glassware. The use of this glassware is not documented in any Quality Control testing records for testing this drug product, including in the LIMS software.

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