DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave,Bldg 51,Rm 4225 Silver Springs, MD 20993 (301)796-3334 Fax:(301)847-8738	5/15/2017-5/23/2017* FEI NUMBER 3008250236

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dr. Govind S. Pandey , Chief Operating Officer & Member of the Board

FIRM NAME	STREET ADDRESS
Sentiss Pharma Pvt. Ltd.	Village Khera Nihla, Tehsil Nalargarh
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
District Solan, Himachal Pradesh, 174101India	Sterile 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

Investigations of an unexplained discrepancy did not extend to other drug products that may have been associated with the specific failure or discrepancy.

A. Review of data integrity issues from 2014 FDA inspection resulted in the following discrepancies: The investigation into the inaccuracies in data records and reporting did not include an assessment into the extent of the data integrity deficiencies or a detailed corrective action plan that describes how you intend to ensure the reliability and completeness of all the data generated in support of submitted filings or a comprehensive description of the root cause of your data integrity lapses. The investigation did not include interviews with microbial or cleaning personnel nor were production videos reviewed from other batches to determine how wide spread the data integrity issues were. In addition, the recording function of the production cameras was eliminated without adequate justification.

B. During receiving, sterile (b) (4) failed sterility on 17 FEB 2015. The resulting investigation determined the firm would increase the sampling for sterility from (b) o (b) (4) and to find a new suppler. During the inspection it was confirmed the firm still only tests (b) (4) of (b) (4) for sterility and are still using the same supplier.

C. (b) (4) can be (b) (4) up to (b) (4) times per procedure N/PR/224/03. Since January 2017, the firm has had to discard (b) (4) out of (b) (4) early due to failure of visual inspection. Of these, (b) (4) (b) (4) were discar d due to (b) (4) while (b) (4) were discarded due to (b) (4) problems. No investigation was opened to determine the cause of the discrepancies or the potential risk to product. The expiry date of the (b) (4) has not been revised.

D. Grade B Cleanroom garbs are allowed to be (b) (4) and reused for up to (b) (4) times per SOP

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N/PR/037/09. Review of garment quality inspection record showed damages were observed at as early as (b) (4) cycles. The firm has not conducted any investigation to document the cause or re-determine the number of (b) (4) cycles allowed.

E. The firm used (b) (4) manufactured by unqualified supplier (b) (4) for sterility testing. The un-inoculated (b) (4) ; negative media control appeared to contain particles; also some of the vials appeared turbid. The firm compares inoculated (b) (4) with negative (b) (4) control for evidence of microbial contamination. The presence of microbial contamination can be missed if comparing to turbid negative media controls.

F. (b) (4) manufactured by unqualified supplier (b) (4) was used in the sterility testing of finished drug products from 09/02/2016 to 09/17/2016. The firm observed media discoloration and subsequently stopped using (b) (4) The firm has not conducted any investigation into (b) (4) quality issue(s), into the reliability on sterility results obtained by using (b) (4) or into impact on product sterility assurance.

OBSERVATION 2

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

A. Validation of the (b) (4) RABS) aseptic fill line:

Media fills:

1. For filling duration, media fill (b) (4) lists the fill time as (b) (4) During the review of the video tape of (b) (4) it was noted that vials were not present on the line for the majority of the time the line was running. For example, (b) (4) specifies filling was performed at (b) (4) on 01 April 2017. Although approximately (b) (4) bottles should have been filled during this duration, only (b) (4) bottles were documented as being filled. Management stated the firm focused on having the filling machine running without bottles on

the line to confirm filling duration.

2. When the filling line is paused, bottles are not left exposed on the line. Interventions simulated during this time are not performed in the presence of bottles on the conveyer.

3. Non-routine media fills are performed prior to and after (b) (4) for assurance of line performance. These media fills do not reflect actual product run times nor do they specify the interventions which need to be performed.

Smoke studies: Turbulence was noted during the review of smoke studies during cap addition.

B. Qualification of aseptic operators: The firm does not have criteria for what needs to be performed by an aseptic operator during a media fill in order to be qualified. All operators who are qualified as an aseptic worker are considered able to do filling as well as set-up operations.

1. (b) (4) operators performed set-up activities during media fill (b) (4), dated (b) (4) while (b) (4) operators only documented the activates being performed. All (b) (4) operators were documented as being qualified to perform set-up activities in the process simulation study report for (b) (4)

2. Management stated the list of the personnel participating in a successful process simulation study would also be considered completing their (b) (4) media fill requirement. The list of participants for media fill (b) (4) includes (b) operators who did not perform any interventions during media fill (b) (4), dated (b) (4)

3. Operators complete additional media fills in addition to the required (b) (4) media fill requirement. Tracking of the media fill requirement for individual operators is updated (b) (4) (b) (6) was qualified during (b) (4) without performing any activities during filling. (b) (6) was also qualified during (b) (4) the only activity he performed in the filling area was simulating the additional of bottles (b) (4) times for a total of (b) (4)

C. Personnel monitoring:

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1. During filling, the firm does not monitoring personnel who work in the grade A area to grade A limits. Instead, filling operators and microbiologists are held to grade B limits during personnel monitoring. It should be noted the filling operator has to use (b) (4) entering through a (b) (4) for the addition caps, bottles and (b) (4) Other interventions are performed (b) (4) the (b) (4) RABs using sterile (b) (4) and not the (b) (4)

2. After set-up of the (b) (4) RABs filling line, only the operators hands are monitored to grade A specifications even through the operators' whole body enters the grade A area during setup. The rest of the PM locations are held to grade B limits. Personnel monitoring counts are noted during review of PM data which would fail if held to grade A limits.

3. An operator is only disqualified from entering into the aseptic area if they don't comply with the acceptance limit (b) (4) times in (b) (4) per SOP N/VP/007/12.

4. Trending of personnel monitoring is not performed on a holistic basis.

D. Poor aseptic technique was noted on the (b) (4) RABS filling line. This is a repeat observation.
   1. Transferring of caps, bottles and (b) (4) into the A area is not performed aseptically.

   2. The (b) (4) RABs filling line uses (b) (4) for access to the grade A area. Prior to (b) (4) the operator wipes the B side of the (b) (4) in an up and down motion. The operator does not wipe the area located directly below the (b) (4) The B area located below the (b) (4) is the area which is touched by the inner side (A grade) of the (b) (4) when (b) (4)

E. (b) (4) BIs are used in the (b) (4) validation of disinfectants, cleanroom garments, machine parts, and manufacturing accessories. The firm has no validation to support the current (b) (4) of (b) (4) for (b) (4) BI package insert specifies (b) (4) The insert further instructs (b) (4) (b) (4) to be validated and determined by the user. The firm lacks scientific justification in using the current (b) (4) for (b) (4) for BI (b) (4)

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OBSERVATION 3

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

A. The (b) (4) temperature incubation of (b) (4) media plates are not validated to demonstrate optimal recovery of a wide range of microorganisms including bacteria, yeast, and mold species. The (b) (4) plates are used in the viable environmental monitoring (EM) and personnel monitoring (PM) of ISO classified areas. After sampling, media plates are incubated (b) (4) (b) (4) The firm has no data to show the (b) (4) incubation at (b) (4) (b) (4) °C is able to support the growth of normal skin flora microorganisms that thrive at body temperature (37°C). Similarly, the firm lacks assurance that the (b) (4) incubation at (b) (4) °C will not suppress the recovery of yeast and mold species that otherwise thrive at ambient temperature.

B. Section (b) (4) of the SOP N/QC/067/23, entitled, "Sampling and Testing of (b) (4) (b) (4) Samples" specifies that (b) (4) samples for microbiological analysis shall be tested within (b) (4) of the collection. Review of source data revealed microbiological analysis of (b) (4) is not always conducted within the specified time frame. This is a repeat observation.

OBSERVATION 4

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications, sampling plans and test procedures designed to assure that components, drug product containers, closures, in-process materials and drug products conform to appropriate standards of identity, strength, quality and purity.

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A. Finished product impurity specifications do not include limits for all process impurities found in the API. These impurities are excluded from the finished product analysis and are not being reported, tracked or trended.

B. N/WH/043/05 Receipt and Issuance of Material other than Raw & Packaging Material procedure, effective 20 April 2016, does not specify the number of (b) (4) sampled during receiving. Management stated QC currently samples (b) (4) regardless of the number of (b) (4) received (up to (b) (4)

It should also be noted that the raw data is not documented from the execution of the (b) (4) test and the firm does not inspect the outer packaging of the (b) (4) for (b) (4) integrity during receiving.

C. During chromatographic analysis, reprocessing is performed on individual sample injections and does not include reprocessing of the system suitability injections.

D. Manual integration of the data is required to be or may be performed during related substances analysis. Clear instructions regarding how to perform manual integration and when manual data integration can or cannot be performed are not provided to ensure consistency.

OBSERVATION 5

The quality control unit lacks the responsibility and authority to approve and reject all components.

SOP SPL-QA-SOP-062-00, entitled, "Vendor Qualification of GMP Consumables" was not followed.

A. The (b) (4) supplier (b) (4) has not been qualified. (b) (4) currently in use on the (b) (4) filling line to make sterile (b) (4) drug products were not inspected or approved by Quality.

B. The firm failed to qualify supplier (b) (4) for critical GMP consumables. Specifically, the firm failed to qualify (b) (4) for (b) (4) media such as (b) (4)

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(b) (4) Despite not being a qualified vendor, (b) (4) manufactured by (b) (4) were used in the sterility testing of drug products.

OBSERVATION 6

Changes to written procedures are not reviewed and approved by the quality control unit.

The following discrepancies were noted during the review of the change control process SPL-QA-SOP-005-06:

A. Documents can be generated outside of the change control system using the CAPA procedure SPL-QA-SOP-015-04. These documents are used on an interim basis until procedures can be updated. These forms are not generated through change control, nor are they tracked or retained after being obsoleted.

B. No document defines what a master working format is. Change control procedure SPL-QA-SOP-005-06 specifies that obsolete master working formats are discarded. The obsolete forms are not achieved.

C. (b) (4) CIs, and BIs are used in the (b) (4) validation of disinfectants, cleanroom garments, machine parts, and manufacturing accessories. We observed quantities and locations of (b) (4) CIs, and BIs being modified without change control management. For example, a total of (b) (4) indicators locations were identified for the initial validation of Maximum Loading Pattern No.-(b) (4) load) for (b) (4) in the (b) (4) filling facility; however, a total of (b) (4) indicators were used in the subsequent (b) (4) revalidation without documented change control process.

OBSERVATION 7

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

The following discrepancies were noted during the review of N/PR/203/09 Cleaning procedure for the (b) (4) Manufacturing and Filling Area and observing the cleaning process of the filling area.

A. The (b) (4) can be used up to (b) (4) prior to discarding). The (b) (4) is used for cleaning the (b) (4) of the (b) (4) RABs (b) (4) prior to cleaning the B area.
B. (b) (4) of (b) (4) is used to rinse the (b) (4) This results in dipping the (b) (4) in 'dirty' (b) (4)
C. During cleaning, a lint-free wipe is used in an up and down motion up to (b) (4) times prior to refolding.

OBSERVATION 8

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

The firm does not take into account mass balance when performing stress studies. During the review of the stress studies performed during the validation of (b) (4) analytical methods, not all peaks were integrated. In one case, approximately 50% of a main peak was missing during one study without generating any impurities. No investigation was initiated and the report states the forced degradation results meet the acceptance criteria.

OBSERVATION 9

Employees engaged in the manufacture and processing of a drug product lack the training and experience required to perform their assigned functions.

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A. There is a lack of documented training of the microbiology staff performing environmental and personnel monitoring of the aseptic fill lines. On 05/22/2017, practical training records of (b)(4) microbiologists who performed routine EM and PM of the aseptic fill lines were reviewed. Microbiologist (b)(6) records list training of the SAS air sampler but no other EM or PM practical training. Microbiologist (b)(6) practical training evaluations contains no documented EM and PM training.

B. The firm's microbiologists stated that bacteria colonies growing close together sharing the same center would be reported as one colony. On 05/19/2017, viable monitoring in sampling and dispensing location (b)(4) date of sampling 05/11/2017-C showed a total bacteria count of (b) CFUs reported by the firm's microbiologist. Reviewed by the FDA microbiologist determined a total of (b) CFUs. Colonies growing closely together but have well defined borders or edges should have been reported as separate colonies.

OBSERVATION 10

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

A. Numbers of EM, PM, and Micro Lab media plates read, discarded, and destroyed cannot be reconciled. For example,

1. On 05/15/2017, a total of (b)(4) media plates were read and released for disposal. Sterilization and Disposal Record of Microbiological Waste (form N/QC/071/01/04) showed a total of (b)(4) plates were (b)(4) discarded.

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2. On 05/14/2017, a total of (b) (4) media plates were read and (b) (4) plates were released for disposal (one plate was retained for isolate identification). Sterilization and Disposal Record of Microbiological Waste showed a total of (b) (4) plates were (b) (4) discarded.

3. On 05/13/2017, a total of (b) (4) media plates were read and released for disposal. Sterilization and Disposal Record of Microbiological Waste showed a total of (b) (4) plates were (b) (4) (b) (4) discarded.

4. On 05/12/2017, a total of (b) (4) media plates were read and released for disposal. Sterilization and Disposal Record of Microbiological Waste showed a total of (b) (4) plates were (b) (4) (b) (4) discarded.

This is a repeat observation.

B. SOP N/QC/189/06 entitled, "Sampling and analysis of (b) (4) packaging materials (Bottle, (b) (4) Cap)" specifies to (b) (4) (b) (4) On 05/15/2017, we observed (b) (4) packaging bottles batch #s (b) (4) (b) (4) were (b) (4) during sterility testing.

C. GTP T/GT/106/10 entitled, "Sterility" specifies to (b) (4) (b) (4) On 05/15/2017, we observed sterile (b) (4) batch #s (b) (4) were not completely (b) (4) during sterility testing.

D. USP <85> Bacterial Endotoxins Test procedure is not followed in that the control standard endotoxin series is not included in the firm's routine endotoxin testing. Controls are necessary to ensure a valid test.

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E. Endotoxin testing via the gel clot method is deficient in that a calibrated thermometer is not utilized to monitor the temperature of heat block used to incubate gel clot test tubes during assays. The firm depends on the heat block digital display for temperature monitoring.

F. On 05/15/2017 we reviewed (b) (4) packaging bottles sterility test source data for batch #s (b) (4) A total of (b) (4) bottles from each batch were tested using (b) (4) media containers with (b) (4) bottles in each container. Despite (b) (4) media containers were incubated and examined for microbial growth (b) (4) only (b) (4) observation was recorded (b) (4) in the worksheet. Similarly, a total of (b) (4) bottles from ea h above batch were tested in (b) (4) media containers with (b) (4) bottles in each container. Despite (b) (4) media containers were incubated and examined for microbial growth (b) (4) only (b) (4) observation was recorded (b) (4) in the worksheet.

***DATES OF INSPECTION**

5/15/2017(Mon),5/16/2017(Tue),5/17/2017(Wed),5/18/2017(Thu),5/19/2017(Fri),5/22/2017(Mon),5/23/2017(Tue)

5/23/2017

X Eileen A Liu

Eileen A Liu
Microbiologist
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