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	2/15/2021-2/25/2021*
	FEI NUMBER 1000251214

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Hisashi Arimoto, General Manager

FIRM NAME	STREET ADDRESS
Toyobo Co. Ltd.	Toyobo (Kabu) Sogokenkyusho, 2 Chome Sogokenkyusho; Katata
CITY, STATE, ZIP CODE, COUNTRY Otsu, Shiga, 520-0292 Japan	TYPE ESTABLISHMENT INSPECTED 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 thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Appropriate microscopic examination of components is not performed.

Specifically,

Defects such as black particles and deformed (b) (4) stoppers have been found through the process of visual inspection of the (b) (4) (b) (4) mg/ml INJ finished drug product vials. (b) (4) stoppers have not been examined to ensure that the sterilization and handling methods do not compromising the integrity of the stoppers and negative impact product quality or sterility assurance.

SOP C503 Solution Formulation Visual Inspection Work Procedure describes the procedure to perform visual inspection of aseptically filled drug product vials. Visual inspection includes review for any defects on the production solution, vial, (b) (4) stopper, and cap. Product Master File Number (b) (4) Manufacturing Outline describes the procedure to perform visual inspection of the drug product vials and document the

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61 foreign particles (black and white); 3 fibers; 30 dirt; and 85 deformed stoppers. Per the firm's management, there has not been any investigations into the nature of these defects, potential impact to product quality, the root cause of these defects, or potential process improvements to prevent future defects.

OBSERVATION 2

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

Specifically,

Environmental monitoring is not continuously measured, recorded, and trended to ensure that Grade A/B/C aseptic filling facilities and equipment are maintained in a state of control. Environmental monitoring trend data contains gaps in the data between 2018-2021 for aseptic formulation filling Building (b) (4) Grade A/B/C areas and for (b) (4) used for (b) (4) Injection (b) (4) mg.

-For example, FY2019 Annual Review Report 4-1-14, covers the period 04/2019-03/2020. The Grade A/B environmental monitoring data trends lack data from 04/2019-07/2019 and reports inconsistent data between 7/26/2019-1/09/2020, and inconsistent data between 1/09/2020-03/30/2020.

-Environmental monitoring data report EM2020 00119 in Building (b) (4) for (b) (4) INJ (b) (4) mg lot (b) (4) reported falsified non-viable particulate count for (b) (4) particles measu at lo (b) (4) with a Grade A limit of (b) (4) particles, with the report modified to falsely report and attribute this data to locatio (b) (4) a Grade B area with limit of (b) (4) particles.

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OBSERVATION 3

Production personnel were not practicing good sanitation and health habits.

Specifically,

-During video review of aseptic production operations of (b) (4) batch lot number (b) (4) from 10/14/2020 and in-person viewing vial washing, stoppering and (b) (4) on 2/17/2021, production personnel were observed doing the following: squatting to the floor below the level of the RABS; sitting; moving rapidly in Grade B areas rather than in careful slow manner; and did not disinfect gloved hands frequently prior to multiple entrance and exits to different rooms and handling of multiple equipment in the Grade B areas and prior to interventions to the Grade A RABs.

-Per the firm's manufacturing and environmental hygiene managers and SOP 4-1-1-2 Hygiene Control Standard, the aseptic operation procedures allow for employees to only sanitize the gloved hands after (b) (4) The procedure states that employees should sanitize after entering and exiting rooms or handling multiple equipment, but the aseptic practices did not appear to be consistent with the stated procedure. The aseptic hygiene procedure states that employees should move slowly and deliberately to avoid spreading particles, but the aseptic practices observed and explanation by the production and hygiene managers was not consistent with the firm's procedure.

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-The firm does not have environmental monitoring data comparing static, dynamic slow movement, and dynamic fast movement to justify the routine activities of production personnel and to provide information to support training for best or improved aseptic practices.

OBSERVATION 4

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

Specifically, during our review of your firm's Quality Control Laboratory electronic chromatography data, deviations from your firms written laboratory control procedures were identified. Our review found that analysis of original test results is not completed, and no laboratory investigation is initiated per your OOS investigation procedure. During our review, it was discovered that your firm was notified by your (b) (4) product sponsor about a new test item per an update to (b) (4) USP monograph, specifically the related substance test. Per your firm, due to pressure from th tion schedule, a decision was made to use raw material (b) (4) Lot No. (b) (4) during manufacture operations, prior to performing the release test for related substance. For this reason, your firm initiated planned deviation No. TC002, dated 03/07/2019, to perform an "investigation" to determine which column and equipment to perform the related substance test item prior to shipping finished product. The following related substance analysis were performed for the planned deviation "investigation" for (b) (4) Lot No. (b) (4)

-The original analysis was performed on 03/13/2019, starting at 11:36 am using HPLC equipment LC07M with the first column of choice. Calculations for related substance individual item impurities and total impurities were not performed by your firm at the time of the analysis. During the current inspection, the calculation for this analysis was performed, and an OOS for (b) (4) compound with results as (b) (4) versus specification of NM (b) (4)

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-A second analysis was performed around the same date and time on 03/13/2019, starting at 11:36 am using HPLC equipment LC09M with a different column. Calculations were performed by your firm at the time of the analysis and found to be within specifications.

-A third analysis was performed on 03/15/2019, starting at 16:27 (4:27 pm) using HPLC equipment LC09M with the same column as the second analysis to confirm original within specification results. Calculation were performed by your firm at the time of the analysis and within specification results were confirmed compared to the second analysis.

After closing the planned deviation, your firm performed the official and reported related substance test on 04/17/2019. As of the current inspection, your firm has not provided an adequate explanation for why the original analysis test results were not calculated and reported. (b) (4) Lot No. (b) (4) was used in the manufacture of (b) (4) finished drug product batches, which have been shipped to the US Market.

OBSERVATION 5

Written production and process control procedures are not followed in the execution of production and process control functions.

Specifically,

Aseptically filled vials of (b) (4) (b) (4) mg/ml INJ, undergoes one hundred percent visual inspection as a quality control measure to ensure integri of the drug product. SOP V002 Visual Inspection Training Procedure was not always followed in the qualification of visual inspectors and the procedure is deficient in defining the vision testing of inspectors.

-The firm does not maintain documentation of (b) (4) ision exams by a qualified doctor or optometrist.

-SOP V002, Revision 4 (page 5), effective 05 February 2021, and prior versions allows visual inspectors to perform a self-test of their eyesight and color vision. The revised SOP indicates a place for a second verifier to sign on the vision test result form. According to the Visual Inspection Manager, the employees may perform and document the results of the test themselves or coworkers may verify each other's vision test results. The actual Vision Test Records of Qualified Vision Testers from 2018-2021 do not have any documented second verifier.

-Per the Visual Inspection Manager, the firm's procedure requires the vision test to be performed every (b) (4) (b) (4) This is not documented on SOP V002 and according to the Vision Test Records of Qualified Vision Testers, the vision tests were completed beyond the (b) (4) on two occasions for each of the (b) (4) inspectors. There is no validation or information in the SOP to justify longer times between vision checks.

-Long term leave of qualified visual inspectors is not documented on the list of qualified inspectors and when the inspector has returned and been requalified.

OBSERVATION 6

Written records of investigations into unexplained discrepancies do not include the conclusions and follow-up.

Specifically,

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Corrective Action/Preventive Action (CAPA's) initiated in response to Data Integrity deficiencies identified and confirmed around April 2020 with Environmental Monitoring operations are not comprehensive to address all potential root causes. For Example:

-CAPA's initiated by your firm described the root cause as "lack of understanding of the GMP and the importance of data integrity", "there was no time for communication, and difficulty in handling deviations and fear for delaying the manufacturing schedule causes psychological pressure", "the person in charge did not understand the purpose and meaning of the measurement of adherent bacteria", "manufacturing personnel did not understand the impact of the number of interventions on the product", and "they did not understand the importance of disinfectants and the rationale for setting expiration dates". Actions taken by the firm included organizing production management desks to be physically near production personnel, establishing one more microorganism specialist to assist in the event of environmental monitoring deviations, starting a program to "invigorate communication within the organization", and performing additional training regarding tasks and data integrity. The CAPA did not evaluate the firm's training program and CAPA implementation in the past in response to significant data integrity deficiencies identified in the Quality Control testing operations around late 2017, early 2018. Specifically, in 2018, your firm identified similar root causes, such as lack of training and lack of awareness regarding the importance of data integrity and performed similar CAPA's such as training and education of personnel. However, approximately 2 years later, your firm has identified additional significant data integrity deficiencies. There is no assurance that current CAPA's in place will lead to long term compliance with data integrity principles at your firm.

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-Your firm initiated temporary deviation No. TC034, dated 09/08/2020, in which Quality Assurance employees are required to be present during all manufacturing operations. Upon review of the temporary deviation and personnel training records, we observed that QA employees observing environmental monitoring and sampling during aseptic operations have not received adequate training with respect to these operations. Additionally, per your firm, due to planned construction for the (b) (4) filling line in early 2021, a campaign to manufacture finished product was planned even prior to the 2020 Data Integrity findings and carried out in the month of October 2020. This temporary deviation was used to manufacture all products at the firm and continues to be used to manufacture product as of the current inspection, with no adequate plans to end this deviation and QA monitoring operations during manufacturing.

- CAPA was initiated to retrieve and review data stored on air samplers used for environmental monitoring operations during manufacture of finished drug product starting 12/28/2020. Per your firm's QC Manager, data stored on the air samplers include, but not limited to, area sampled, volume sampled, time sampled, end date/time, flow rate, target volume, warnings, alarms, and operator. Per your procedure QA081, titled 'How to check records of environmental monitoring devices', your system administrator will retrieve the data and compare this data to paper records within (b) (4) (b) (4) This procedure does not consider the timeline to release finished drug product, since data from a (b) (4) of interest, leaving the potential for releasing drug product without reviewing raw data. In addition, your firm has not validated your portable air samplers used for environmental monitoring during manufacturing operations to assure that stored data is retrievable, reviewable and secure from alteration.

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OBSERVATION 7

The suitability of all testing methods is not verified under actual conditions of use.

Specifically,

Your firm has not performed the process of assessing the suitability of a compendial analytical test procedure under the actual conditions of use for a specified drug product. During our review, it was discovered that your firm was notified by your product sponsor about a new test item per an update to (b) (4) USP monograph for related substance test method. Per your firm, due to pressure from the production schedule, a decision was made by your management to use raw material (b) (4) during manufacture operations of (b) (4) drug product, prior to performing the release test for related substance. For this reason, initiated a planned deviation, to perform an "investigation" to determine which column and equipment to perform related substance test item prior to shipping finished product. After a series of analyses using two different columns and two different HPLC equipment, your firm determined to use a specific column with a specific HPLC equipment. As of the current inspection, no official protocol, report, or adequate analyses has been performed by the firm with respect to test method verification for (b) (4) related substance test method. Additionally, your firm does not maintain a procedure to perform t hod verifications of USP compendial methods.

OBSERVATION 8

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,

-The list of observations noted in this document portray that the Quality Unit has not performed the necessary assessments/reviews to ensure that the objectionable conditions do not negatively affect the manufacturing process and Quality Control tests in support of the finished drug products.

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-There is a lack of Quality Unit oversight over controlled documents. Your firm does not maintain an established cGMP document control procedure and does not have a way of tracking discarded records by the Quality Unit. During the inspection, we identified the following, but not limited, uncontrolled documents inside cardboard boxes used for discarding documents in the Quality Control and Manufacturing office of Building No. (b) (4) Deviation Investigation Reports, Deviations Correction Reports, CAPA Implementation Plan, and blank uncontrolled QC test worksheets. When the draft reports found in the shred box were compared to the official reports, information on these records did not always match. Additionally, investigation related content observed on email communications between the firm and a third-party entity were not always described in the firm's official reports.

-During our walkthrough of the QC laboratory (b) (4) and QA office (b) (4) Building No. (b) (4) a document stamping machine with individu o print unique i ps on QC test worksheets were observed. However, the room in which this equipment and SD cards are located are not secure, in that the door is never locked at the end of business days, and personnel do not lock drawers in which SD cards are stored.

-The firm's Quality Agreement and Complaint Handling Procedure lacks provisions that allow for the firm as a contract finished drug manufacturer to receive at least summary information of all product complaints and adverse event reports to allow for the quality control unit to investigate potential systemic issues to determine if there are product manufacturing or handling processes that may contribute to product quality issues.

-There is no data integrity program in place to include a statistically sound representative review of all electronic data by the Quality Unit to ensure completeness, consistency, and accuracy of all chromatographic raw data generated by the Quality Control laboratory.

-There is no adequate procedure describing the standardized naming systems for electronic test data generated by the HPLC and GC systems.

OBSERVATION 9

Batch production and control records do not include the weights and measures of components used in the course of processing each batch of drug product produced.

The following executed batch production records and master batch record (b) (4) for (b) (4) were reviewed: (b) (4) The batch production and control records are deficient in that they do not include:

-the amount of drug substance (b) (4) used in the formulation of finished drug product; and

-identification of the persons performing and checking each significant step in the operation.

Specifically,

-The amount of (b) (4) to the formulation is not recorded in the executed batch production records. The records do not include a calibration of the scale used for weights and measures of (b) (4) and other reagents added to the formulation tank.

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-Per the manufacturing manager, (b) (4) ottles of (b) (4) are used per batch production of drug product formulation. Each bottle of (b) (4) (b) (4) accomplished by (b) (4) employees. However, the batch records do no identify each person involved in performing the (b) (4) of this critical agent in the formulation.

-The amount of (b) (4) s not calculate and reported in the batch production records, directly or as a s tical agent in the formulation.

OBSERVATION 10

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically,

Your firm has not validated your portable air samplers used for environmental monitoring during manufacturing operations to assure that stored data is retrievable, reviewable and secure from alteration. Your firm maintains approximately (b) (4) air samplers with data storage capabilities which have been in operation starting from the year 2016. Per your firm's QC Manager, data stored on the air sampler include, but not limited to, area sampled, volume sampled, time sampled, end date/time, flow rate, target volume, warnings, alarms, and operator. In response to data integrity deficiencies identified around April 2020, your firm initiated a CAPA in which starting 12/28/2020 all air sampler equipment data is to be retrieved from air samplers by your system administrator and provided to your Quality Assurance Unit for review.

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OBSERVATION 11

Employees are not given training in the particular operations they perform as part of their function and current good manufacturing practices.

Specifically,

In response to Data Integrity deficiencies with respect to environmental monitoring operations during production identified by your firm around April 2020, your firm initiated temporary deviation No. TC034, dated 09/08/2020, in which Quality Assurance employees are required to be present during all manufacturing operations. Upon review of the temporary deviation and personnel training records, we observed that QA employees observing environmental monitoring and sampling during aseptic operations have not received adequate training with respect to these operations. There is no assurance that QA personnel are qualified to evaluate and determine whether proper environmental monitoring and aseptic techniques are utilized during aseptic operations.

*DATES OF INSPECTION

2/15/2021(Mon), 2/16/2021(Tue), 2/17/2021(Wed), 2/18/2021(Thu), 2/19/2021(Fri), 2/22/2021(Mon), 2/24/2021(Wed), 2/25/2021(Thu)

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