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	11/13/2025-11/21/2025* FEI NUMBER 3004055563

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Masakazu Miyashita, Factory Director

FIRM NAME	STREET ADDRESS
Sato Pharmaceutical Co., Ltd.	1468, Hazama-Machi
CITY, STATE, ZIP CODE, COUNTRY Hachioji, Tokyo, 193-0941 Japan	TYPE ESTABLISHMENT INSPECTED OTC Drug Manufacturer (Sterile and Non-Sterile)

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 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,

Your firm initiated Deviation Investigation 2020-083 following the detection of Bacillus cereus in the media fill conducted on June 23, 2020. According to your investigation, non-procedural overheating occurred due to the addition of (b) (4) water exceeding (b) (4) °C (actual temperature measured above (b) (4) °C) during (b) (4) media preparation. This elevated temperature caused the liquid to create a vacuum effect in the (b) (4) valve, resulting in air ingress from the non-sterile (b) (4) side of the valve. Your firm removed the (b) (4) valve and replaced it with a (b) (4) pipe that has no valve, removing the pipes physical connection to the drain.

Following the requalification of the line pursuant the aforementioned media fill failures, your firm performed a plumbing renovation on the aseptic line that included, but was not limited to, (b) (4) (b) (4) Following these renovations, your firm has continued to experience numerous media fill failures with visible particle contamination found to be present in the (+) media bottles from the (b) (4) Aseptic filling line which is located in the Manufacturing Building, (b) (4)

Your firm failed to adequately investigate these media fill failures, to identify the root cause and implement appropriate corrective and preventive actions for both bacterial and foreign matter contamination. These media fill failures continue to identify Bacillus cereus, as well as numerous other organisms as the causative agent. The following table shows the identification of the bacteria found to contaminate the (+) media filled bottles and the

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	Anastasia M Shields, Investigator Nibin Varghese, Investigator X Anastasia M Shields Investigator Signed By: ANASTASIA M. SHIELDS -S Date Signed: 01-05-2026 18:18:42	1/5/2026

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various types of particles found in the (+) media fill bottles.

Date	Deviation No.	Bacteria detected	Foreign body detected
2022/11/22	2022-124	Microbacterium paulum	Rayon, (b) (4) polyester, recycled paper
2023/1/24	2023-013	Microbacterium paulum	Cellulosic fibers
2023/6/15	2023-071	Paenibacillus glucanolyticus or Paenibacillus lautus Pseudomonas putida group Staphylococcus warneri Niallia taxi Cytobacillus gottheilii	Polyester, protein-based substances, rubber possibilities, acrylic fibers, dark blue cotton fibers, iron-rich substances, silicon-rich substances
2024/4/11	2024-048	Bacillus cereus group,Bacillus altitudinis or Bacillus pumilus Peribacillus simplex or Peribacillus muralis. Bacillus cereus group,Bacillus zhangzhouensis or B. safensis or B. pumilus Bacillus cereus group	Sand grains,(b) (4) acrylic fibers, (b) (4) iron materials, (b) (4) polyester, (b) (4) plantfragments, cotton fibers

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2025/1/9	2025-005	Paracoccus yeei Pantoea vagans or Pantoea agglomerans Bacillus cereus group Bacillus subtilis group Bacillus pumilus Massilia alkalitolerans, Massilia oculi,Massilia timonae or Massilia varians Cladosporium sp. (Estimated) Priestia megaterium Bacillus pumilus or Bacillus altitudinis Paenibacillus amylolyticus, Paenibacillus cucumis, Paenibacillus taichungensis, Paenibacillus tundrae or Paenibacillus tylopili Niallia circulans Psychrobacillus sp. Apiospora saccharicola or Apiospora dichotomanthis	(b) (4) fiber scraps made of cotton fibers and polyesters, spinning fibers such as wool, cotton fibers, polyesters, paintflakes (alkyd resin systems), (b) (4) plantfragments, inorganic substances containing a lot ofsilicon, calcium, iron, organic matter(proteins), rayon, (b) (4) silicon, etc., polyester, (b) (4) materials
2025/2/20	2025-040	Aerococcus urinaeequi or Aerococcus viridans, Bacillus pumilus, Dermacoccus sp.,Moraxella osloensis	(b) (4) material, paint fragments、 (b) (4) inorganicsubstances containing a lotofiron, etc.

This line is used to fill the US market OTC (b) (4) products, (b) (4)

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OBSERVATION 2

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

Specifically,

A. Your firm's airflow visualization studies performed in the (b) (4) Filling Line, (Protocol Smoke and Existing (b) (4) 004-P) which is used to aseptically fill OTC (b) (4) for the U.S. market, failed to show smoke that is uniformly supplied and covering the entire airflow cascade from HEPA filter to the working area to demonstrate the presence or absence of turbulence.

1. Your firm generates smoke for your airflow visualization studies by (b) (4) There is no evidence to show that the smoke generated is neutrally buoyant.

2. Your firm utilizes a (b) (4) to discharge smoke for the smoke study. The is being manually held approximately (b) (4) the HEPA filter. The space between the HEPA filter and pipe used to discharge smoke is not evaluated as part of the smoke study.

3. Your firm's (b) (4) utilized to discharge smoke during your smoke study, is not held perpendicular to the direction of the air being evaluated. Instead, it is held pointing upwards, directly into the source of the air being discharged from the HEPA filter resulting in the air reversing direction and immediately hitting the pipe supplying the smoke. This makes it difficult to evaluate the direction of the air flow and any turbulence, if it is present, within the aseptic filling area.

4. Your firm's (b) (4) that is used to discharge smoke during the smoke study is manually maneuvered and operated. During the review of the smoke study conducted per Protocol Protocol VMP-000-P-01, the employee holding this manifold was observed moving it around the area of activity on the line being reviewed impeding the visibility of airflow and any associated turbulence.

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B. The design of the aseptic area does not promote unidirectional air flow, specifically in the event of a (b) (4) (b) (4) intervention conducted on the aseptic filling line. The air intake vents for the Grade A LAF (b) (4) RABS) are located above the RABS (b) (4) on the filling line at the ceiling level. When the (b) (4) is (b) (4) it will draw the air upward off the line resulting in first pass air not reaching the level of the filling line.

OBSERVATION 3

The accuracy, sensitivity, specificity and reproducibility of test methods have not been established and documented.

Specifically,

During the review of stability data for multiple drug products, it was observed that your firm's HPLC chromatographic analysis did not monitor or report an impurity peak consistently eluting before the main peak. This early-eluting impurity was visible in the chromatograms but was not integrated, identified, or evaluated against established acceptance criteria. The following are examples of drug product stability data observed with early-eluting peaks, but the deficiencies are not limited to:

a) 12-months and 24-months stability data for (b) (4) Lot # (b) (4) show an early-eluting peak before the (b) (4) peak, with a retention time of approximately at (b) (4) (b) (4) This peak was not observed during the release testing. According to your firm, this peak was an impurity peak and is currently not monitored or reported during the stability studies.

b) 12-months stability data for (b) (4) Lot # (b) (4) show early eluting peaks before the (b) (4) peak, with retention times of approximately at (b) (4) These peaks were not observed during the release testing.

OBSERVATION 4

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

Specifically, your firm initiated OOS 2024-004 for failing stability sample test results at the 24-month time mark

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for long term stability (25±2°C/60±5% RH), (b) (4) Batch (b) (4) for the assay test for (b) (4) API, (b) (4) % (specification (b) (4) %). Retesting was performed using the retain sample for that same lot resulting in an out of specification result for assay of (b) (4) % (against (b) (4) %). Your firm's Quality Unit failed to assess the impact of this stability failure and make a market action decision on the respective batches still within expiry.

OBSERVATION 5

The written stability testing program is not followed.

Specifically,

During the stability data review of several of your Over The Counter (OTC) products, it was observed that your firm failed to test the assay during the 12-month timepoint. Your firm revised procedure *Document No. QTS-040: Stability Test Procedure* to eliminate the 12-month stability testing time point without adequate scientific justification. This revision removes a critical testing interval from your stability program, compromising the assessment of product stability characteristics over the intended shelf life. The following are the examples of the product stability lots where I observed the firm eliminated 12-month assay testing, but the deficiencies are not limited to:

(b) (4)

OBSERVATION 6

The written stability program for drug products does not include specific test methods.

Specifically,

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Your stability testing program does not include complete test parameters necessary to adequately assess product stability characteristics. Review of stability protocols and testing records revealed that critical quality attributes are omitted from routine stability testing. The following are examples of the drug product stability testing program that does not include complete test parameters, but the deficiencies are not limited to:

a) (b) (4) - The stability study omits (b) (4) degradation products, (b) (4) content, and dose uniformity.

b) (b) (4) - The stability study omits (b) (4) content, degradation products, particulate matter, and weight loss.

OBSERVATION 7

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

Specifically,

Your firm manufactured and released several Over The Counter (OTC) products to the US market without conducting required microbiological testing, including testing for Burkholderia cepacia. All your products contain (b) (4) as an inactive ingredient in the formulations, which significantly increases the microbiological risk profile and necessitates comprehensive microbiological testing to ensure product safety. The following are the examples of products released without conducting required microbiological testing

a) (b) (4) Lot #(b) (4) Expiry (b) (4)
b) (b) (4) Lot #(b) (4) Expiry (b) (4)
c) (b) (4) Lot #(b) (4) Expiry (b) (4)

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OBSERVATION 8

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

Specifically, your firm's disinfectant efficacy study, Protocol # (b) (4) entitled, "Efficacy Evaluation of (b) (4) Disinfectant Solutions for Use within Sato Pharmaceutical Facilities Located in Tokyo Japan", for the (b) (4) aseptic filling line, failed to assess the sporicidal and bactericidal effect of (b) (4) (b) (4) on the material (b) (4) of which the (b) (4) used to hold the sterile (b) (4) bottles into place on the filling line, are constructed.

OBSERVATION 9

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

Specifically,

During the walkthrough inspection of your manufacturing facility, it was observed that the equipment used for the manufacturing of Over The Counter (OTC) products is not maintained at appropriate intervals to prevent malfunctions and contamination. The following are the examples, but the deficiencies are not limited to:

a)The tablet compression machine (b) (4) located on the (b) (4) used for the manufacturing of (b) (4) tablets (b) (4) showed visible wear/damage to (b) (4) (b) (4) components, particularly evident in the safety guard areas. The damaged (b) (4) can shed fragments due to equipment vibration and mechanical stress during compression operations. It was also observed that a zip tie was used to control the (b) (4) from the main (b) (4) The last batch manufactured for the US market using this compression machine was on December 05, 2024, for Lot #(b) (4)

b)During the inspection, it was observed that the (b) (4) filling line located in Plant (b) (4) had visible

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corrosion/rust on the lower portion of the (b) (4) component. The corroded area appears as (b) (4) discoloration on the external surface of the (b) (4) machine. The visible corrosion/rust is approximately 8 cm above the open bottle with product. This equipment is used in the manufacture of (b) (4) for the US market. The presence of corrosion on drug manufacturing equipment presents a risk of contamination to the drug product and may compromise product quality, safety, and efficacy. Additionally, this condition indicates that the firm's equipment maintenance and inspection procedures may be inadequate to ensure equipment is maintained in proper condition. The last batch manufactured for the US market using this filling machine was on July 22, 2024, for Lot # (b) (4)

OBSERVATION 10

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

Specifically, your firm's operators working in the Grade A and B areas are using goggles which have holes on the top that open directly to the outside (direct vent).

*DATES OF INSPECTION

11/13/2025(Thu), 11/14/2025(Fri), 11/17/2025(Mon), 11/18/2025(Tue), 11/19/2025(Wed), 11/20/2025(Thu), 11/21/2025(Fri)

AMENDMENT 1

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."