

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION							
DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857		DATE(S) OF INSPECTION 4/7/2025-4/11/2025					
		FEI NUMBER 3010806039					
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Mr. Dipti Samant, Managing Co-Coordinator							
FIRM NAME Blossom Pharmaceuticals		STREET ADDRESS 21/22 Tivim Industrial Estate, Karaswada					
CITY, STATE, ZIP CODE, COUNTRY Bardez, Goa, 403526 India		TYPE ESTABLISHMENT INSPECTED OTC 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 I OBSERVED: OBSERVATION 1 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. Specifically, your firm failed to ensure that manufacturing processes are consistently performed and documented in accordance with established written procedures. Batch production records (BMR/BPR), sampling activities, deviations, and validation studies are incomplete, inaccurate, falsified, or not attributable to the personnel performing the activities. Your production system lacks adequate control over documentation, personnel accountability, and verification of critical steps. Examples include, but are not limited to: A. Batch records are deficient in that they lack attributability for multiple products, including but not limited to: • (b) (4) USP (b) (4) B. No. (b) (4) • (b) (4), B. No. (b) (4) • (b) (4) B. No. (b) (4) • (b) (4) B. No. (b) (4) were found to be completed by supervisory personnel after operations took place and not by the operators who performed the work. Your Senior Production Supervisor, and Production Manager, confirmed they complete all batch records. Operators do not record their activities or sign the BMR/BPR.							
SEE REVERSE OF THIS PAGE		<table border="0" style="width: 100%;"> <tr> <td style="width: 60%;"> EMPLOYEE(S) SIGNATURE Kellia N Hicks, Investigator </td> <td style="width: 40%; text-align: center; vertical-align: bottom;"> Kellia N Hicks Investigator Signed By: KELLIA N. HICKS -6 Date Signed: 04-11-2025 19:07:59 </td> </tr> <tr> <td></td> <td style="text-align: center;"> </td> </tr> </table>		EMPLOYEE(S) SIGNATURE Kellia N Hicks, Investigator	Kellia N Hicks Investigator Signed By: KELLIA N. HICKS -6 Date Signed: 04-11-2025 19:07:59		
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Batch records are not completed contemporaneously. For example, on 08 Apr 2025, I observed that the BMR for (b) (4), B. No. (b) (4) was largely blank, even though dispensing had occurred, raw materials were staged, and the manufacturing suite had been accessed without documented line clearance. The Senior Production Supervisor confirmed that the (b) (4) pages of the BMR should have been completed but were not started. In the BMR for (b) (4) B. No. (b) (4), the following fields were left incomplete: • No actual or theoretical yield recorded. • No QA signature verifying critical process parameters or product conformity. • No documentation of semi-finished bulk sampling • No reconciliation signed by QA or Production in-charge. Sampling is not documented, and sampling techniques are not representative. For pH testing, your Senior Production Manager stated, "We just take a spatula and skim from the top and take it to QC." There is no documentation of the sampling event, who performed it, or a defined sampling method. B. On 07 Apr 2025, I observed falsification in the batch packaging record (BPR) for (b) (4), B. No. (b) (4). Operator (b) (6) reported to have recorded tare weights for shippers without weighing them. For example, she recorded (b) (4) g as the tare weight, while the actual measured weight was (b) (4) g. Multiple unsigned and undated entries were present in the BPR. Additionally, Page (b) (4) of the BPR was copied multiple times based on the number		
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of boxes packed, indicating that no control exists over master production records and the documentation is reproducible and falsifiable.

C. Your firm failed to complete process validation for the full range of batch sizes manufactured for U.S. marketed drug products including:

- (b) (4)
- (b) (4)
- (b) (4)
- (b) (4), and others (b) (4)

Your firm manufacture multiple un-validated batch sizes for each product at customer request without demonstrating process consistency. Since the previous inspection, 122 deviations have occurred, 103 **(84.4%)** of which were due to batch size changes without corresponding validation.

D. Your firm failed to validate the ERP System used for batch release. Per procedure "SOP/QA/33, Revision 07, SOP for Release of Batch", final product release is performed through an ERP system that has not been validated.

OBSERVATION 2

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

Specifically, your firm failed to establish and follow adequate written procedures for cleaning and maintenance of equipment to prevent contamination or carryover of materials. For example, but not limited to the following:

A. Your firm failed to use adequate and validated cleaning processes to prevent cross-contamination for

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all equipment which is non-dedicated, and used in the manufacture of multiple drug products, including, but not limited to, (b) (4). Cleaning operations are inadequately documented, inconsistently executed, and not properly validated. Examples include, but are not limited to: 1. On 08 Apr 2025, I observed dispensed raw materials and excipients staged in Manufacturing (b) (4) Suite for (b) (4), Batch No. (b) (4). Equipment in this room, including Manufacturing Vessel (b) (4) OT-040, and (b) (4) Vessel, OT-024, had not been cleaned from the previous product. No line clearance had been performed or documented prior to staging these materials. The Senior Production Manager reported there was no other place to store the already dispensed material. 2. On 07 Apr 2025, (b) (4) Storage Tank OT-007-1, labeled "CLEAN," was observed to have (b) (4) residue from (b) (4) on contact. Your Senior Production Manager confirmed the label was applied in error. 3. Manufacturing Vessel OT-036 was observed with visible (b) (4) residues and stained surfaces despite being labeled clean. Cleaning was reported to have been done on 05 Apr 2025 but was undocumented. 4. OT-033 (b) (4) Vessel) was labeled clean, but no corresponding cleaning entry was found in the logbook. 5. OT-008-3 (b) (4) Filling Machine) had an exposed (b) (4) while labeled clean, with no protective covering. 6. Staff in (b) (4) Filling (b) (4) were observed wiping the (b) (4) Filling Machine with non-lint-free towels. Management referred to this as "wiping cleaning," but confirmed this method is not described in any written procedure and was not documented.			
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Furthermore, the cleaning validation studies conducted were deficient, lacking: - Justification and evaluation of worst-case products. - Calculation of Maximum Allowable Carryover (MACO). - Defined sampling plans and sampling location justifications. - Residue testing for the previous product (only cleaning agent tested). - Risk assessment for cleaning effectiveness and residue carryover. Clean and dirty hold time studies failed to: - Include worst-case molecules or conditions. - Include clear sampling instructions and rationale. - Test for product residues over defined holding periods. - Include <u>ALL</u> Manufacturing ^(b) equipment, which are used in the manufacture ^{(b) (4)} batch sizes.			
OBSERVATION 3 Written procedures are not established and followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product. Specifically, your firm failed to maintain and ensure the accuracy, reliability, and integrity of records and signatures used to document equipment cleaning and maintenance activities in cleaning and use logs that are attributable to the individuals performing the work, accurate, complete, and contemporaneously documented.			
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For example, but not limited to:

- I observed multiple pieces of equipment labeled "CLEAN" that were visibly unclean and for which no cleaning was documented in the logbooks. These include, but are not limited to:
 - (b) (4) Storage Tank OT-007-1
 - Manufacturing Vessel OT-036
 - (b) (4) Vessel OT-033
 - (b) (4) Filling Machine OT-008-3
- I reviewed the equipment cleaning and use logs for Type A Cleaning for Manufacturing Vessel OT-036 (EQ ID: OT-036). The logs were completed by the Senior Production Supervisor. Cleaning durations from 2023 to current [2025] ranged from (b) (4) to (b) (4). (b) (4) However, your firm's cleaning methodology procedure specifies at least (b) (4) cleaning steps, each with a designated minimum time, requiring a minimum of (b) (4) to complete. Management confirmed that all steps cannot be properly performed in less than (b) (4).
- I reviewed Type B Cleaning logs for OT-036, which is conducted batch-to-batch in campaign manufacturing. The logs show durations as short as (b) (4), despite no established or validated procedure for Type B Cleaning. Cleaning time ranged from (b) (4) to (b) (4).
- Similarly, for (b) (4) Vessel OT-033 (EQ ID: OT-033), the Type A Cleaning log entries from 2023 to current, also completed by the Senior Production Supervisor, report cleaning durations ranging from (b) (4) to (b) (4). As with OT-036, the stated minimum leaning time per procedure is (b) (4), and cleaning under (b) (4) may indicate incomplete or inaccurate records.
- For Type B Cleaning of OT-033, logs show cleaning durations from (b) (4) to (b) (4). Again, no cleaning procedure exists for Type B Cleaning, and no validation has been performed.

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to support the cleaning effectiveness or appropriate duration. Cleaning entries were routinely made by supervisory staff who did not perform the cleaning. Your Senior Production Supervisor reported that operators do not sign or document activities; instead, supervisors complete and sign all records regardless of who performed the work.			
OBSERVATION 4 Laboratory controls do not include the establishment of scientifically sound and appropriate specifications, standards and test procedures designed to assure that in-process materials and drug products conform to appropriate standards of identity, strength, quality and purity. Specifically, laboratory test methods used for raw material and finished product testing are not verified or validated to ensure accuracy, sensitivity, specificity, and reproducibility. Your firm failed to verify or validate the analytical test methods used for raw material acceptance testing. This includes, for example, assay testing of active pharmaceutical ingredients (APIs) by high-performance liquid chromatography (HPLC), which are used in the manufacture of OTC drug products. These methods have not been demonstrated to be suitable under actual conditions of use. No data was provided to support the accuracy or reproducibility of this method for its intended purpose. Additionally, none of the microbiological test methods used for finished product release testing, including total microbial enumeration testes (aerobic microbial count, total yeast and mold count), and testing for the absence of specified microorganisms, including, but not limited to, <i>staphylococcus aureus</i>, <i>Pseudomonas aeruginosa</i>, and <i>Candida albicans</i> have been validated or verified for any OTC drug product. Your firm failed to establish data to show these methods are appropriate for the specific product formulations or capable of reliably detecting microbial contamination under actual testing conditions.			
OBSERVATION 5			
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Buildings used in the manufacture, processing, packing, or holding of a drug product do not have the suitable to facilitate cleaning, maintenance, and proper operations. Specifically, your firm failed to maintain adequate air-handling systems to ensure suitable environmental conditions are provided where drug products are processed. On 07 Apr 2025, the Air Handling Unit (AHU) in the "Liquid (b) (4) Filling" area was observed to be non-operational. Your Manager, Production Planning, reported the AHU was "tripped" but could not provide a work order or documentation of the failure, notification, or any corrective actions. During this time, im-process bulk for filling, (b) (4) (Batch # (b) (4)) was being stored in this room at a temperature of 26°C, exceeding the validated upper limit of 25°C with labeled "To be Cleaned" [dirty] equipment, Filling Machine EL-003. No deviation or CAPA was initiated. Additionally, your firm failed to install AHUs in Quarantine Rooms (b) (4) to ensure environmental control for bulk in-process material for all products which are stored in Quarantine Rooms (b) (4) for up to (b) (4) prior to filling operations. In another example, on 07 Apr 2025, I observed in-process bulk (b) (4) B. No. (b) (4), (b) (4) B. No. (b) (4), (b) (4) B. No. (b) (4), and (b) (4) B. No. (b) (4) to be stored in Quarantine room (b) (4) with out of service/broken equipment, dirty equipment labeled to cleaned and for the temperature of the room to have exceeded the bulk storage conditions 23C + or- 2C. The temperature was reading 26C. The room also had broken covings and walls. On 08 Apr 2025, as a corrective action, the firm moved the (b) (4) to another location which was also had unclean equipment and the temperature was exceeding the 25C upper limit.			
OBSERVATION 6			
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Bardez, Goa, 403526 India

TYPE ESTABLISHMENT INSPECTED

OTC Manufacturer

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

Specifically, your Quality Unit failed to adequately exercise its authority and responsibilities, including but not limited to, ensuring data integrity, implementing effective procedures, and conducting adequate oversight to support the safety, effectiveness, and quality of the drug products you manufacture. For example, but not limited to:

A. Your firm failed to perform Process Validation (PV), Cleaning Validation (CV), and/or Cleaning Verification for Product Changeover and Batch to Batch Cleaning for all US marketed products as confirmed by your Production Management and QA Manager. You utilize non-dedicated equipment to manufacture US marketed products. You established a clean hold time (CHT) of (b) (4) and a dirty hold time (DHT) of (b) (4) for equipment without performing adequate studies to support the CHT and DHT. You currently manufactured approximately (b) (4) US marketed products and (b) (4) products for the rest of the world (ROW) at your facility. For example, but not limited to, US Marketed Products:

(b) (4)

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Kellia N Hicks
Investigator
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B. Deviations from written production and process control procedures are not recorded and justified. For example, but not limited to the following: 1. Your Manager, Production Planner reported, deviations occurring during the manufacturing process are not documented in the batch manufacturing record (BMR). 2. During the walkthrough of the facility on 07 Apr 2025, I observed that no batch records for in-process batches were contemporaneously completed. For example, I observed (b) (4) B. No, (b) (4) operations to have finished and the, but the BMR was not complete. The following items were left blank: the Actual and Theoretical Yields, QA did not sign to verify the critical process parameter, the semi-finished product bulk sampling report was not completed, there was no QA signature for "Product manufactured according to the specification, and the BMR reconciliation was not signed by the Production In-Charge or the QA In-Charge. The Senior Production Manager reported that he completes this section, but he doesn't sign. No deviation investigation was initiated, and no justification was provided. Other batches without contemporaneous batch records include, but are not limited to the following:			
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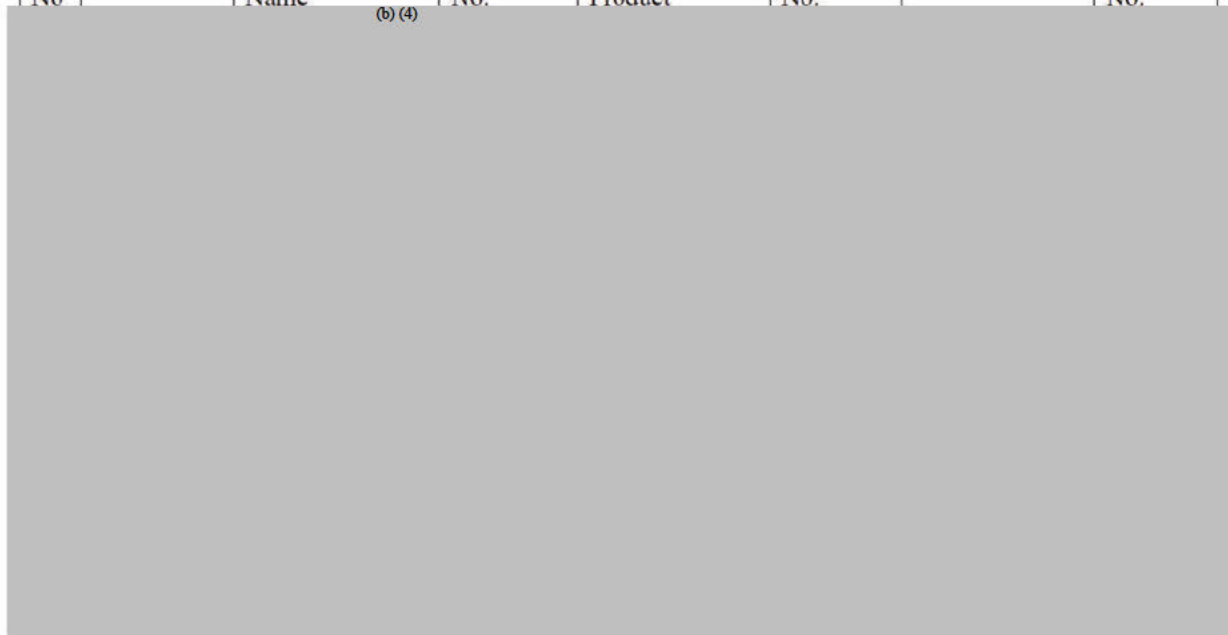
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Sr. No	Mfg. Area	Equipment Name	Equipment No.	Previous Product	Batch No.	Next Product	Batch No.
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The Senior Production Manager reported that the batch record is normally completed by himself later.

- On 07 Apr 2025, I observed the (Non-Dedicated) (b) (4) Vessel (b) (4) OT-033, located in Manufacturing (b) (4) to have an equipment cleaned status tag but cleaning was not recorded in the Equipment Cleaning and Use Logbook. This equipment is used in the manufacture of all (b) (4) (b) (4) US marketed products) manufactured at your facility. No deviation investigation was initiated, and no justification was provided.

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4. On 08 Apr 2025, I observed (b) (4) BMR for B. No. (b) (4), was largely blank. However, dispensing for the product had occurred and the raw materials and excipients were stored in the manufacturing suite, "Manufacturing (b) (4)". The equipment in this room, including, but not limited to, Manufacturing Vessel (b) (4) OT-040 and (b) (4) Vessel, OT-024 had not been cleaned from the previous product and line clearance had not been performed or documented. The Senior Production Manager confirmed up to page (b) (4) of the batch record should have been completed but was not started. No deviation was initiated, and justification was provided. 5. On 08 Apr 2025, I observed Operator Saff in (b) (4) Filling (b) (4) where the equipment was labeled to be filling (b) (4) B. No. (b) (4), to be cleaning the (b) (4) Filling Machine EQ ID: OT-008-3, with dirty towels that are not lint free clothes. Present Production Management reported that they were conducting "Wiping Cleaning". He further reported this is not an established in a cleaning procedure, and that the cleaning was not documented. No deviation investigation was initiated, and no justification was provided. 6. On 07 Apr 2025 I touched (non-dedicated) (b) (4) Storage Tank OT/07-01, which was labeled to be clean, and (b) (4) substance transferred to my hand that was reported by the Senior Production Manager to be (b) (4). He acknowledged, "This is dirty, the tag is wrong." No deviation investigation was initiated, and no justification was provided. C. Your failed to perform a Quality Risk Assessments or initiated change controls from inception to date when you introduced the (b) (4) US marketed products and (b) (4) Rest of the World (ROW) products into your facility as per procedure, "SOP-QA/43, Revision 02, SOP for Risk Management by Failure Mode Effect Analysis and Root Cause Analysis, Effective Date: 30 Jan 2025". D. Your firm failed to establish, implement, and/or follow quality control procedures including, but not limited to the following:			
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Type-B Cleaning Field Alert Reporting							
OBSERVATION 7 Employees are not given training in the particular operations they perform as part of their function and current good manufacturing practices. Specifically, your firm failed to maintain adequate records demonstrating that all laboratory employees had completed required training programs relevant to their job functions. 1. Your firm failed to train (b) (4) of (b) (4) % current employees on cGMP training. There was no evidence that ALL employees conducting critical laboratory activities had received training in current Good Manufacturing Practices (cGMPs) and Good Laboratory Practices (GLPs). Additionally, your firm failed to integrate 21 CFR 211 into the cGMP training program. Your firm's current cGMP training materials do not include specific requirements from 21 CFR 211, which provides critical guidance on Good Manufacturing Practices for drug manufacturing. This omission limits personnel understanding of essential quality standards specifically relevant to drug product production. Your firm failed to maintain adequate training records. Training records for employees were either incomplete or not maintained. Employees working in critical areas, such as the (b) (4) production and packaging (b) (4) %, do not have documented evidence of training in the operations they perform including proper documentation practices (BMR).							
SEE REVERSE OF THIS PAGE		<table border="0" style="width: 100%;"> <tr> <td style="width: 60%; vertical-align: top;"> EMPLOYEE(S) SIGNATURE Kellia N Hicks, Investigator </td> <td style="width: 40%; vertical-align: top; text-align: center;"> DATE ISSUED 4/11/2025 </td> </tr> <tr> <td style="vertical-align: bottom; text-align: right;"> Kellia N Hicks Investigator Signed By: KELLIA N. HICKS -6 Date Signed: 04-11-2025 19:07:59 </td> <td style="vertical-align: bottom; text-align: center;"> X </td> </tr> </table>		EMPLOYEE(S) SIGNATURE Kellia N Hicks, Investigator	DATE ISSUED 4/11/2025	Kellia N Hicks Investigator Signed By: KELLIA N. HICKS -6 Date Signed: 04-11-2025 19:07:59	X
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER

12420 Parklawn Drive, Room 2032
Rockville, MD 20857

DATE(S) OF INSPECTION

4/7/2025-4/11/2025

FEI NUMBER

3010806039

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mr. Dipti Samant, Managing Co-Coordinator

FIRM NAME

Blossom Pharmaceuticals

STREET ADDRESS

21/22 Tivim Industrial Estate, Karaswada

CITY, STATE, ZIP CODE, COUNTRY

Bardez, Goa, 403526 India

TYPE ESTABLISHMENT INSPECTED

OTC Manufacturer

APPEARS THIS
WAY ON
ORIGINAL

SEE REVERSE
OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Kellia N Hicks, Investigator

Kellia N Hicks
Investigator
Signed By: KELLIA N. HICKS -6
Date Signed: 04-11-2025
19:07:59

X

DATE ISSUED

4/11/2025