

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 5/12/2025-5/20/2025* FEI NUMBER 3005719315				
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Agnieszka Lubkowska, Site General Manager						
FIRM NAME Watson Pharma Private Limited		STREET ADDRESS Plot No. A3 - A6, Phase 1-A, Verna Industrial Estate				
CITY, STATE, ZIP CODE, COUNTRY Verna, Salcette, Goa, 403722 India		TYPE ESTABLISHMENT INSPECTED Drug Product 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 Separate or defined areas to prevent contamination or mix-ups are deficient regarding the manufacturing and processing operations. Specifically, your firm has failed to implement adequate cross-contamination controls to ensure drug products manufactured at your site are not contaminated by the residues from (b) (4) drug products. For example: A. Your firm has been manufacturing (b) (4) drugs, (b) (4) Tablets (b) (4) mg (b) (4) Tablets (b) (4) mg, (b) (4) Tablets (b) (4) mg and (b) (4) Tablets (b) (4) mg (b) (4) using equipment and rooms that are shared with other (b) (4) drug products. Sampling, dispensing, (b) (4) areas and equipment used for (b) (4) drug products are shared with approximately (b) (4) other (b) (4) US drug products. After Sampling, dispensing, (b) (4) of (b) (4) (b) (4) drug products, you use these areas to sample, dispense and manufacture other (b) (4) (b) (4) drug products without any verification by appropriate testing that these areas, equipment, and air is free from residues of (b) (4) drug products. B. You don't have adequate cross-contamination prevention and control plans for routine sampling & monitoring of facilities, personnel, air supply, and equipment at appropriate intervals to demonstrate (b) (4) drug products, manufactured at the site using shared facilities, equipment, and air handling systems are not being cross-contaminated with the traces of (b) (4)						
SEE REVERSE OF THIS PAGE		<table border="0" style="width: 100%;"> <tr> <td style="width: 60%;"> EMPLOYEE(S) SIGNATURE Tamil Arasu, Investigator - Dedicated Drug Cadre Lauren N Howard, Investigator </td> <td style="width: 20%; text-align: center; vertical-align: bottom;"> X </td> <td style="width: 20%; vertical-align: top;"> DATE ISSUED 5/20/2025 Lauren N Howard Investigator Signed By: Lauren N. Howard -G Date Signed: 05-20-2025 03:41:57 </td> </tr> </table>		EMPLOYEE(S) SIGNATURE Tamil Arasu, Investigator - Dedicated Drug Cadre Lauren N Howard, Investigator	X	DATE ISSUED 5/20/2025 Lauren N Howard Investigator Signed By: Lauren N. Howard -G Date Signed: 05-20-2025 03:41:57
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(b) (4) drug products. Your risk assessment, QRA/24/005-02, has not led to adequate controls to prevent cross-contamination and monitor for (b) (4) drugs. You have released approximately (b) (4) batches of drug products for the US market that were manufactured using the shared equipment and facility. C. Your cleaning validation and verification studies of the major manufacturing equipment for the worst-case drug products do not include studies for monitoring of traces of the (b) (4) product, (b) (4) and do not include risk factor associated with the (b) (4)					
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, A. (b) (4) Tablet, (b) (4) mg strength, packaged batch number (b) (4) (bulk batch number (b) (4) tested over the acceptable intake limit on November 7, 2023, as part of a (b) (4) risk assessment completed by your firm for (b) (4) impurity (b) (4) (result (b) (4) acceptable intake limit (b) (4) Your firm did not perform an investigation into the high impurity result and did not perform any additional testing on the impacted batch or other (b) (4) mg batches still within expiry. Additionally, at the time the high (b) (4) impurity result was confirmed, your firm failed to test (b) (4) other (b) (4) Tablet (b) (4) mg batches still within expiry for possible high levels of (b) (4) impurities. Your firm failed to file a Field Alert Report (FAR) for the confirmed high result. (b) (4) Tablet, (b) (4) mg strength is still actively manufactured at your site without performing testing for (b) (4) impurities prior to release. (b) (4) Tablet (b) (4) mg, packaged batch number (b) (4) (bulk batch number (b) (4) expiration date (b) (4) and has not been evaluated for (b) (4) impurities.					
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B. Your firm extended the shelf life of (b) (4) Capsules (b) (4) from (b) (4) to (b) (4) on 03-15-2023 (Change Control# 2524084). However, you have recorded 5 OOS investigations for this product since February 2022. All of them were for dissolution test and were found to be valid OOS results. Though you have rejected all the (b) (4) batches that were manufactured since the initial OOS was observed, you have not identified the root cause and addressed the dissolution issue adequately. The probable root causes identified could not be adequately supported. For example, combined Deviation investigation approved on 03-29-2023, attributed the probable root cause to the 'API characteristics & high variability in dissolution results due to analytical method'. C. Complaint investigations are inadequate in finding the root causes and resolving the continued complaints for the product, (b) (4) Tablets USP (b) (4) for defective tablets including broken tablets. Of the approximately total number of 151 complaints received for this product since Jan 2023, approximately 32 complaints were relating to defective tablets. However, your investigations have not identified appropriate root causes and you have not adequately addressed this issue and you have concluded that "there is no evidence to support that the reported defect could have originated from Manufacturer's end".			
OBSERVATION 3 Control procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product. Specifically, A. According to your firm's Associate Director Plant/Site Quality Assurance, (b) (4) visual inspection and beyond is performed if the tightened AQL conducted by the Quality Unit fails following 100% visual inspection. This is not outlined in procedure SOPG016755_7, "Product Inspection for Physical Defects." Since 2023, the following (b) (4) finished product batches still within			
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FOOD AND DRUG ADMINISTRATION**

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Agnieszka Lubkowska, Site General Manager

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expiry required additional visual inspection beyond the 100% visual inspection stated in your procedure.



(b) (4) Tablets (b) (4) mg, bulk batch number (b) (4) failed to meet batch yield specification (result (b) (4) %, specification (b) (4) %) due to an elevated number of rejects detected during multiple rounds of visual inspection (passed after (b) (4) visual inspection). This batch was released and distributed to the U.S. market by your firm.

(b) (4) Tablets (b) (4) mg, bulk batch number (b) (4) underwent (b) (4) visual inspection before finally passing AQL. Deviation number 2753727 was opened on October 27, 2023, and concluded the root cause was due to a (b) (4). Despite this conclusion, the batch was released and distributed to the U.S. market.

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B. During the current inspection, on May 19, 2025, 100% visual inspection for (b) (4) Tablets (b) (4)mg, bulk batch number (b) (4) was being performed by (b) (4) operators in which all rejects from (b) (4) operators were placed in (b) (4) container. Number of defects for each defect type identified by the operators were not being recorded contemporaneously. Per your firm's Associate Director Plant/Site Quality Assurance, 100% visual inspection is routinely conducted at the site in this manner.

***DATES OF INSPECTION**

5/12/2025(Mon), 5/13/2025(Tue), 5/14/2025(Wed), 5/15/2025(Thu), 5/16/2025(Fri), 5/19/2025(Mon), 5/20/2025(Tue)

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Investigator - Dedicated Drug Cadre
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