



DISTRICT ADDRESS GMP Trends® P.O. Box 266 Bound Brook, NJ 08805		DATE OF ISSUE December 1, 2025	
		C.I. ISSUE Issue #1173	
NAME AND TITLE OF INDIVIDUALS TO WHOM REPORT IS ISSUED To: Responsible Person, Director of Quality Assurance			
FIRM NAME Pharmaceutical and Related Industries		STREET ADDRESS 5600 Regulation Lane	
CITY, STATE AND COUNTRY United States of America and Worldwide		TYPE OF ESTABLISHMENT INSPECTED Pharmaceutical and Medical Device	
DURING A REVIEW OF INSPECTION REPORTS OF FIRMS (I) (WE) OBSERVED: <u>EDITED EXCERPTS FROM ACTUAL 483 OBSERVATION REPORTS BY FOOD AND DRUG ADMINISTRATION INVESTIGATORS</u> QUALITY SYSTEMS			
1. Procedures for training and identifying training needs have not been adequately established. Specifically, a. Operators who conduct machining of raw materials, assembly, and finishing have not been trained in your firm's nonconformance procedure SOP ..., "Control of Nonconforming Product". A review of 11 training records revealed 6 operators who have not been trained in this procedure. These individuals perform in-process inspections and have the ability to reject/accept devices. However, they are not required to be trained on the nonconformance SOP. b. Operators who conduct final cleaning using the ... Cleaning Machine (model ...) have not been adequately trained in your firm's nonconformance procedure SOP ..., "Control of Nonconforming Product". For example, operators ... and ... who were trained on operating temperatures associated with WI-..., "... Cleaning", operated the ... at temperatures colder than the specified limits. This occurred on multiple times over the last 5 months. Moreover, your firm's management representative stated that cleaning operators are only trained to identify nonconformances regarding damage to parts and products.			
2. The responsibilities and procedures applicable to the quality control unit are not in writing. Specifically, a. Your firm does not have procedures in place and lacks written documentation on reporting and reviewing of Temperature Mapping, stability for ... and ... bulk, sample retain, manufacturing codes, Annual Product Review, Vendor Agreement Procedure, process validation protocol for the manufacturing of ... products. b. Lack of qualification of the ... water system used in the manufacturing and cleaning production equipment's of ..., ..., and There is no monitoring for Conductivity and Total Organic Carbon (TOC) for this water system. Your firm fails to justify not testing ... water system for conductivity and TOC daily. c. Your firm's procedure SOP ..., "Deviation Control", does not specify a required timeframe for closing out deviations. d. Your firm does not have a procedure for issuing batch numbers and controls for creation of batch numbers.			
3. The responsibilities of the Quality Unit are not in writing or fully followed. Specifically, there is no written procedure documenting the responsibilities of the quality unit, including the release of incoming raw materials, review of batch records, qualification of suppliers, and the issuance, control, and reconciliation of labels.			
4. Procedures for quality audits have not been adequately established. Specifically, your firm did not document and maintain the ... internal audit record forms used and completed by your internal auditor who conducted the one-day full quality system audit 2 years ago. You did not have the completed Audit Plan Form and Audit Report Form, as required by your procedure SOP ..., "Quality System Audits".			
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DURING A REVIEW OF INSPECTION REPORTS OF FIRMS (I) (WE) OBSERVED:			
MANUFACTURING CONTROLS			
1. Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.			
<p>Specifically, there are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess. Specifically, the Process Validation (PV) for ... Tablets is deficient for the following reasons:</p>			
a. Protocol No: ... states that ... tablets from each side of the tablet press will be collected at ... of the compression cycles. However, there is no documentation of the time when samples were collected to represent the ... of the compressions cycles in the Batch Manufacturing Record (BMR) for PV Lot# ... Additionally, ... samples were collected after compression cycles for PV Lot# ..., but only composite samples were collected after compression of lot #s ... and ...; as such, inter-batch and intra-batch variability was not assessed.			
b. No dissolution testing was performed on the final coated tablets for the ... PV lots and no dissolution testing is performed during stability studies.			
c. The firm placed ...on stability studies; however, no scientific rationale was provided for why ... placed on stability studies.			
2. Equipment and utensils are not maintained at appropriate intervals to prevent malfunctions and contamination that would alter the safety, identity, strength, quality or purity of the drug product.			
<p>Specifically,</p>			
a. You failed to adequately maintain your packaging line equipment located in Room ... which is used to fill your prescription drug products into their primary packaging. You used clear packaging tape to maintain and repair your packaging line turntable used to feed open primary packaging containers onto the filling line. You used clear packaging tape to maintain and repair a plastic cover located directly above open and filled containers of drug product on the filling line conveyor belt immediately after the ... Equipment ID: And you used brown tape to maintain and repair the Capper, Equipment ID: ..., directly above open and filled containers of drug product before the bottles were capped and sealed. You utilize the packaging line equipment to manufacture your prescription drug products.			
b. You failed to adequately maintain your ... tablet Press, Equipment ID: located in manufacturing Room ... You installed ... fittings in the vacuum exhaust lines on the top of the equipment which are each connected to a vacuum unit. The top connection of both ... fittings were wrapped with clear packaging tape to increase the suction of the vacuum inside the tablet press. You utilize the ... Tablet Press to manufacture your prescription drug product ...			
3. 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.			
<p>Specifically, your firm has not completed a cleaning validation for your processes and equipment used to produce your finished drug product ..., and ... The equipment is non-dedicated and used in the processes involving both drug products.</p>			
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DURING A REVIEW OF INSPECTION REPORTS OF FIRMS (I) (WE) OBSERVED: STERILE MANUFACTURING CONTROLS		
<p>1. Personnel were observed conducting aseptic manipulations or placing equipment/supplies in an area that blocked the movement of first pass air around uncapped syringes, whether before or after it is filled with sterile product.</p> <p>Specifically, we observed the following during the inspection:</p> <p>a. During the preparation of ..., Lot: ..., we observed your employee's gloved hand directly over an open syringe in a ... orientation that blocked first pass air in the ... ISO 5 LAWf.</p> <p>b. During the preparation of ... Lot: ..., your employee was observed working above the syringe of open ... product, having their gloved fingertips touch the hub of the syringe, handle the ... with their gloved fingertips at the downstream end of the ... and using their gloved fingertips to touch the filling needle while blocking first pass ISO 5 air flow. Furthermore, your employee was observed placing their gloved hand directly over the sterile vials before drug product intended to be sterile was introduced into the vial.</p> <p>c. During the preparation of a hazardous drug, ..., Lot: ... we observed your employee holding the ... drug product filled syringe ... position with the filling needle pointing away from first pass air in your ISO 5 Biological Safety Cabinet (BSC). Your employee was observed transferring the ... drug product from the syringe to another syringe and proceeded to move the ... syringe in ... and away from first pass ISO 5 air. Furthermore, we observed your aseptic employee had an excess of materials and trash on the grill of the biological safety cabinet as they prepared drug products intended to be sterile.</p>		
<p>2. Drug product samples are not representative of the entire batch and properly identified.</p> <p>Specifically, finished product release testing sample sizes did not appear to be representative of the size of the batch and a review of a list of ... batches of ... vials with expiration dates from ... to ... found that the largest batch in the documentation provided was lot The batch size for lot ... is less than half of the largest batch size. The finished product samples submitted for batch release testing by the contract test lab for the largest batch lot ... was ... vials and for the smallest batch lot ... was ... vials. The batch size and number of ... vials tested for sterility was not identified on the contract test lab finished product test report. The method Non-Component Standard Test Method Finished Goods and Stability Testing for ... Vials identifies the sterility sample size for product release as ... vials per ... of ran selected ... throughout ... of the batch. This did not include a consideration for the batch size.</p>		
<p>3. Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established.</p> <p>Specifically, you do not disinfect or sanitize surfaces of the ... filling/stoppering machine and ... interior after contact by production operators during post disinfection open door critical setup operations and open ... door filling interventions before closing the ... doors and initiating or resuming filling operations. Furthermore, all interventions requiring access within the ... are performed by opening ... doors since the ... is not fitted with gloves. During the inspection, operators were observed opening the ... filling/stoppering machine ... at the filling zone to perform fill weight checks during filling of ... Lot # The filling zone door was closed to begin filling without disinfecting or sanitizing potential operator contacted surfaces to include the interior of the ... door.</p>		
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DURING A REVIEW OF INSPECTION REPORTS OF FIRMS (I) (WE) OBSERVED:

MEDICAL DEVICE-MANUFACTURING CONTROLS

1. Written MDR procedures have not been developed.

Specifically, your firm does not have a written procedure for initiating and submitting a Medical Device Report. Your SOP ..., "Corrective and Preventive Action Control Procedure", and SOP ..., "Complaint Handling Control Procedure" does not specify MDR guidance or direct information towards MDR instructions. When asked about Medical Device Reporting, your firm did not have adequate information on the understanding of these requirements.

2. Products that do not conform to specifications are not adequately controlled.

Specifically, your firm's Return Materials Authorization Log lists 11 RMA numbers and your NCR Procedures states that all material returned under the RMA form are considered nonconforming, however, your NCR log is blank and no NCR's were on file.

3. Procedures have not been adequately established to control product that does not conform to specified requirements.

Specifically, during your review of NCR ... concerning inaccurate lot number on device label for your ... device, you failed to document if rework had an adverse effect on the product in accordance with your SOP ..., "Control of Non-Conformance".

4. Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been adequately established.

Specifically, the firm could not provide evidence of approval and evaluation of key suppliers for the ... components and services per the firm's SOP..., "Purchasing Process Procedure".

5. Procedures or instructions for performing servicing activities and verifying that servicing meets specified requirements have not been adequately established.

Specifically, your firm's Quality Manual requires your firm to maintain written servicing procedures, however, your SOP ..., "Service and Repair- Procedure", contains no procedures and only states that service and repair is not conducted by your firm. Additionally, your Quality Manual requires service report review, however, service reports review was not documented. Vendor quality audits have not been conducted as required by your Vendor Qualification Procedure. Moreover, your agreement with your sole distributor requires the distributor to service your device, however, the agreement expired 13 years ago.

6. Procedures for design validation have not been adequately established.

Specifically, the ... Testing Summary provided as the firm's design validation for the ... did not include acceptance criteria or a rationale for the sample size of ... collecting ... for ... participants. Additionally, patient characteristics, such as presence of nail polish, skin temperature, skin pigmentation, or conditions which may cause low perfusion, were not documented.

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