

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 5/12/2025-5/16/2025 FEI NUMBER 3008920776					
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Vince P. Pileggi, President							
FIRM NAME VitaCare Labs Inc.		STREET ADDRESS 1186 Cardiff Blvd					
CITY, STATE, ZIP CODE, COUNTRY Mississauga, L5S 1P6		TYPE ESTABLISHMENT INSPECTED Contract OTC 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 I OBSERVED: PRODUCTION SYSTEM							
OBSERVATION 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. Specifically, This is a REPEAT OBSERVATION from the inspection conducted 10/22/2018 to 10/26/2018. <u>Unqualified and Undefined: When Process Validation Fails to Deliver</u> During a regulatory compliance review of your validation program on 05/13/2025, your Quality Unit provided several process validation (PV) reports for the following OTC (b) (4) drug products: (b) (4) While reviewing the reports, several critical quality failures demonstrate the inadequate of your validation program for OTC (b) (4) drugs. Issues identified include:							
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i. Industrial (b) (4) filling equipment are not qualified for their intended use. For example, validation reports failed to specify a suitable operational range for (b) (4) using only the term “(b) (4)”. ii. The validation program has not adequately defined critical process parameters and critical quality attributes. For example, the (b) (4) of the (b) (4) was not designated as a critical process parameter in the process validations, despite being mandated for monitoring by production in batch records (b) (4). Furthermore, (b) (4) was not established to ensure (b) (4). iii. Data supporting bulk hold times and established critical quality attributes for (b) (4) operations is absent from your validation program. iv. The validation program has not defined process parameters and critical quality attributes for filling operations, specifically addressing the various (b) (4) unit containers used for the U.S. market. (b) (4) <u>But Not Proven: Validation Gaps in Your (b) (4) System Control</u> Since the previous inspection from 2018, your firm uses (b) (4) as a drug component to manufacture OTC (b) (4) drug products. Your Quality Unit has yet to validate that the (b) (4) (b) (4) system is sufficiently designed, controlled, maintained, and monitored to ensure it consistently produces (b) (4) fit for its intended use. This is a REPEAT VERBAL OBSERVATION from the inspection conducted 10/22/2018 to 10/26/2018. <u>Preventing Cross-Contamination: Cleaning Validation Gaps</u> On 05/12-13/2025, confirmation from your Quality Unit and Production Manager verified that all manufacturing equipment is non-dedicated and used for commercial batches of (b) (4) OTC drug products for the global market. No scientific justification was given as to why the cleaning validation only used the (b) (4) (Lot (b) (4); EXP: (b) (4)			
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(b) (4) (u) (4) while omitting the (b) (4) The review of your cleaning validation program uncovered several critical failures related to the insufficient identification of all plausible worst-case conditions for (b) (4) fillers. The program fails to address scenarios involving products with elevated toxicity and potency levels, products that demonstrate low solubility in cleaning solvents, and those formulations that are inherently difficult to clean based on their characteristics. In addition, the program does not specify the identification of challenging swabbing locations, and define maximum hold times before cleaning operations commence, thereby compromising the overall effectiveness of your cleaning procedures.			
OBSERVATION 2 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, This is a REPEAT OBSERVATION from the inspection conducted 10/22/2018 to 10/26/2018. Your firm neglected to adequately clean and maintain non-dedicated equipment used for manufacturing over-the-counter (b) (4) drug products. <u>Elevated Risk of Cross-Contamination</u> On 05/12/2025, I conducted an extensive inspection of your (b) (4) tank 11 and (b) (4) filler (b) (4) equipment previously used by your Production Manager during the cleaning validation of lot (b) (4) for (b) (4) on 03/27/2025. Since then, your Production Manager confirmed that these equipment have not been used to make any commercial products. Given the current state of			
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the equipment, my findings indicated an elevated risk of cross-contamination for lot (b) (4) I observed visible presence of unidentified (b) (4) inside the tank at the (b) (4) and on the manifold (b) (4) valve, including dark residual defects near the (b) (4) port. Your Production Manager and I discovered a dead leg in the (b) (4) tubing system for the (b) (4) filler 2 that had not been addressed by the Quality Unit before the inspection. Subsequent investigative measures involved removing the tubing, which resulted in stagnant (b) (4) rapidly flowing out from the (b) (4) tubing system along with traces of (b) (4) fluid on the ground. Upon reviewing the cleaning validation batch record, your production manager performed (b) (4) for the tubing system on 03/27/2025. <u>Erosion Exposure: Addressing (b) (4) Corrosion in Industrial Equipment</u> On 05/12/2025, the apparent (b) (4) corrosion was discovered on several (b) (4) in (b) (4) tank 8, which has been used for manufacturing commercial batches of OTC (b) (4) drugs since the previous inspection in 2018. Your production manager noted that your quality unit failed to establish a robust cleaning program with effective (b) (4) practices for the (b) (4) tank's (b) (4) in the batch record. Examples of cleaning and process validation batches can be referenced in the following table. Since 2018, your Quality Unit and Production Manager failed to detect, report, and investigate the observed corrosion on (b) (4) components. For instance, your Quality Unit neglected to replace the (b) (4) gasket within the (b) (4) valve prior to the inspection, and only after I found the warped gasket did your firm decide to rectify the critical infrastructure failure by buying a new (b) (4) valve and (b) (4)			
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<u>Cracking Under Pressure: Compliance Challenges in Corrosion and Leaks</u> Observations made during the walkthrough with your Production Manager on 05/12/2025 indicated deficiencies in the periodic maintenance of industrial equipment used in OTC drug product manufacturing. For instance, I observed a collection tray placed directly beneath the cracked, leaking (b) (4) pipping in the (b) (4). Your Quality Unit explained (b) (4) is a drug component used in the manufacturing of OTC (b) (4) formulations. (b) (4) Referring to the table, I requested the batch records denoted in blue highlights. Additionally, the industrial hose on (b) (4) tank 7 was observed to be leaking, and patched with clear adhesive tape. The use of an industrial hose is required to (b) (4) transfer OTC bulk (b) (4) solutions to the liquid filling equipment (b) (4) using (b) (4).			
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OBSERVATION 3 Batch production and control records do not include complete information relating to the production and control of each batch. Specifically, Batch production and control records for OTC (b) (4) drug products lack essential CGMP requirements necessary for process reproducibility. Additionally, your quality unit uses non-validated Excel spreadsheets to make changes for all master batch records. <u>Missing Paper Trail: When (b) (4) Sanitization Goes Unverified</u> On 05/14/2025, while reviewing batch record of lot (b) (4), your Production Manager detailed that (b) (4) sanitization had been carried out before operating (b) (4) tank 7 and (b) (4) filler 3. To explain how the filler's attached tubing is sanitized, a written justification narrative was provided outlining the sanitization process for filler (b) (4). Referring to the batch record, there are no supporting documents to corroborate that (b) (4) sanitization was performed contemporaneously prior to using any production equipment. <u>Compliance in Question: When Cleaning Guidelines Lack Clarity</u> The cleaning and sanitization form (VC-025) lacks explicit directives regarding equipment disassembly. It instructs production staff to dismantle (b) (4) utensils, (b) (4) pipes, gaskets, (b) (4) and (b) (4) "if necessary" but fails to define the conditions requiring disassembly. Without clear criteria, your production team cannot reliably identify when (b) (4) clean is required, leading to potentially inconsistencies in cleaning and sanitization procedures. This is a REPEAT OBSERVATION from the inspection conducted 10/22/2018 to 10/26/2018.			
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<u>Under the Radar: The Hidden Risks of Inadequate Sampling Protocols</u> Deficiencies have been noted in the batching procedure for (b) (4) operation, filling setup sheet, and packaging instructions. Specifically, these documents do not include detailed protocols for sampling and testing during in-process control, final product release, and stability assessments. Moreover, there are no written procedures in place for sampling products designated for retained storage.			
LABORATORY CONTROL SYSTEM			
OBSERVATION 4 The written stability testing program is not followed. Specifically, This is a REPEAT VERBAL OBSERVATION from the inspection conducted 10/22/2018 to 10/26/2018. <u>Customer Satisfaction Over Compliance: Stability Testing Vanished</u> Your firm's stability program (VC-SOP-Q-303.2) states that once long-term data confirms a product's shelf life, one lot each year is selected for continuous stability testing. Despite this requirement, your Quality Unit prioritized customer satisfaction over fulfilling regulatory compliance, which led to the omission of the required stability testing for every marketed OTC (b) (4) product since 2023. Examples of the commercial batches were reviewed with your quality unit to identify which timepoints your contract laboratory had last completed. (b) (4)			
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Referring to the table, process validation lots are highlighted in red, while (NA) signifies that a batch record for lot (b) (4) is not available. Since 2023, your firm manufactured and distributed the following quantities of OTC (b) (4) drug products to the U.S.			
OBSERVATION 5 Laboratory controls do not include the establishment of scientifically sound and appropriate specifications and test procedures designed to assure that components conform to appropriate standards of identity, strength, quality and purity. Specifically,			
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From Purity to Uncertainty: The Compliance Gap in (b) (4) Testing

As of October 2023, your Quality Unit discontinued (b) (4) testing on (b) (4) (b) (4) samples collected from Ports (b) (4) from these ports is utilized as a drug component in the formulation of commercial OTC (b) (4) drug batches, as described in the accompanying table. Failure to continuously monitor a critical quality attribute (CQA) like (b) (4) for a component used in drug manufacturing poses a significant risk to product quality and is a regulatory compliance deficiency.

(b) (4)

This is a REPEAT OBSERVATION from the inspection conducted 10/22/2018 to 10/26/2018.

Consistency Through Compliance: The Need for Formalized Physical Testing Procedures

Currently, your Quality Unit has not established any formal, documented laboratory procedures for assessing (b) (4) in both in-process samples and finished products.

QUALITY SYSTEM

OBSERVATION 6

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

Specifically,

Your investigations into elevated microbial counts for the (b) (4) samples lacked sufficient root

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cause determinations, CAPA, and assessment of all potentially affected OTC (b) (4) drug batches. <u>Quality Conundrum: A Microbial Crisis Unveiled</u> INV 2023-001: On 07/25/2023, total plate counts for (b) (4) ports (b) (4) (b) (4) cfu/mL) and (b) (4) (b) (4) cfu/mL) exceeded the established limit of NMT (b) (4) cfu/mL. A detailed review of the investigation revealed that the Quality Unit did not thoroughly assess the potential root causes of these high microbial counts. In Phase 1, your quality unit ruled out laboratory errors, stating that “everything was correct from the (contract) lab”. However, no supporting documents, such as a signed written OOS investigation report from the contract manufacturer, were provided to substantiate this conclusion. Additionally, the quality unit did not furnish evidence demonstrating that the sampling technique adhere to the (b) (4) sampling and testing procedure (VC-SOP-Q-219.4). During Phase 2, your production manager explained that the (b) (4) samples were collected when the (b) (4) was off due to a full storage tank (b) (4). Despite this, the investigation report did not include a timeline indicating the last usage of the (b) (4) system. INV 2023-003: As part of the corrective action for INV 2023-001, both ports were sampled and retested on 08/02/2023. Your quality unit noted that the reanalyzed microbiological data indicated port (b) (4) yielded (b) (4) cfu/mL – far above the threshold of no more than (b) (4) cfu/mL – while port (b) (4) result of (b) (4) cfu/mL was acceptable. On 09/05/2023, investigation 2023-003 was initiated, during which the contract laboratory disclosed that the samples were mishandled as a result of laboratory maintenance activities. The findings in this report echoed the quality issues identified in INV 2023-001. Additionally, your Quality Unit failed to carry out a thorough on-site audit to explain why laboratory reports were issued on 08/25/2023, despite the fact that both samples were received on 08/03/2023, and no inquiry was made into all potentially affected OTC (b) (4) batches produced in August 2023.			
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