DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313)393-8139	2/26/2026-3/5/2026* FEI NUMBER 1818911

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Marco Cesar Minarro Cremasco, General Manager - Personal Care

FIRM NAME	STREET ADDRESS
Accra-Pac, Inc.	1919 Superior St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Elkhart, IN 46516-4707	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 WE OBSERVED:

OBSERVATION 1

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically,

a. **[REPEAT OBSERVATION]**
Your firm has given "Analyst" role with the same privileges to the software system, (b) (4) to all the analytical lab personnel, including the analyst, the supervisor, and the manager. Some of the privileges including, but not limited to, deleting sequence, delete method, manual integration, modify method properties, load data and sequence from not configured path, reprocess, etc. (b) (4) is the software system installed in HPLC/GC for the testing of raw materials and finished drug products. During the walkthrough of the laboratory on 3/4/2026, after the QC Laboratory Supervisor logged into (b) (4), the QC Laboratory Supervisor was able to change the date and time on the computer.

b. The written procedures do not clearly delineate data backup responsibilities. Two procedures address data backup but contain conflicting information: ELKH-QA-SOP-0688, "Computer System Back-Up Requirements" (effective 3/10/2025), and ELKH-QC-SOP-0835, "Laboratory Documentation, Review and Data Storage Procedure" (effective 6/30/2025). One procedure assigns data backup responsibility to QC, while the other assigns it to IT.

c. The documentation of the (b) (4) audit trail review performed was insufficient in that

there were no traceability to the batch number nor the material/ product name that was being reviewed.

OBSERVATION 2

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,

Your firm's process validation for (b) (4) and (b) (4) does not include scientific data or rationale to support the (b) (4) of (b) (4) to (b) (4) (b) (4) used during manufacturing of these drug products. According to ELKH-VAL-SOP-0852, "Process Validation Master Plan," (b) (4) is defined as a Critical Process Parameter but it was not evaluated in the process validation for the aforementioned products. Your firm has shipped and released (b) (4) lots of (b) (4) and (b) (4) lots of (b) (4) to the U.S. market since February 2024.

OBSERVATION 3

Records are not kept for the cleaning of equipment.

Specifically,

Your firm has established and validated a dirty hold time (DHT) of (b) (4) for (b) (4) compounding tanks in the (b) (4) Compounding Area, which are used in the manufacture of drug products and cosmetics. However, the logbooks associated with these compounding tanks do not document the start and stop

times for tank usage and cleaning. There are no controls in place to record how many hours the tanks have been in "dirty" status, or to ensure that the (b) (4) dirty hold time is not exceeded to prevent cross-contamination.

OBSERVATION 4
Written procedures are not followed for the approval of components.

Specifically,

Your firm failed to follow your written procedures for qualifying new or existing raw material (active ingredient and excipient) suppliers. According to your written procedures CORP-QA-SOP-1887, titled "Supplier Selection, Qualification, and Maintenance", your firm failed to perform site audit for Risk Level I suppliers (active ingredient suppliers), and failed to perform site audit/ self-assessment for Risk Level II suppliers (suppliers including but not limited to, (b) (4) at the specified frequency. The active ingredients (b) (4) and (b) (4) are used in OTC drug products (b) (4) powder for (b) (4) treatment and (b) (4) spray, respectively.

OBSERVATION 5
All compounding and storage containers used during the production of a batch of drug product is not properly identified at all times to indicate contents.

Specifically,

Your firm failed to establish adequate controls and procedures to prevent mix-ups of (b) (4) tankers used in the manufacture of OTC aerosol drug product.
During the facility walkthrough, (b) (4) (b) (4) tankers (tank numbers (b) (4) (b) (4) (b) (4)) were observed parked on the (b) (4) tanker lot. The tankers displayed only tank numbers and lacked labels or placards indicating their receiving status and contents. Content information for the tankers was displayed on a "(b) (4) Board" located approximately 30 feet away from the (b) (4) tankers. In addition, the tank numbers were

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not shown on the (b) (4) Board, making it difficult to determine which (b) (4) tanker corresponded to the "(b) (4) (b) (4) and which corresponded to the "(b) (4) (b) (4) as stated on the (b) (4) Board. Your firm receives (b) (4) different types of (b) (4) as (b) (4) tankers.

***DATES OF INSPECTION**

2/26/2026(Thu), 2/27/2026(Fri), 3/02/2026(Mon), 3/03/2026(Tue), 3/04/2026(Wed), 3/05/2026(Thu)

X WenNing Chan
Investigator
Signed By: 2003086020
Date Signed: 03-05-2026 17:29:27

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Amatul H Marium, Investigator
WenNing Chan, Investigator

X Amatul H Marium
Investigator
Signed By: AMATUL H. MARIUM
Date Signed: 03-05-2026
17:28:35

DATE ISSUED
3/5/2026

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."