

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER Kansas City District 8050 Marshal Drive, Suite 250 Lenexa, KS 66214 (913) 495-5100	DATE(S) OF INSPECTION 02/23/2026, 02/24/2026, 02/25/2026, & 02/27/2026
	FEI NUMBER 3009690111

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Steven C. Stumpf, Vice President Quality

FIRM NAME Hillyard GMP	STREET ADDRESS 226 Robidoux Street
CITY, STATE, ZIP CODE, COUNTRY Saint Joseph, MO 64504	TYPE ESTABLISHMENT INSPECTED 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:

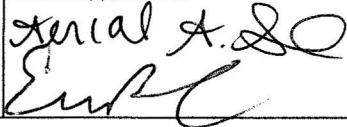
OBSERVATION 1 (QUALITY SYSTEM)

Written procedures for the qualification and approval of suppliers of components were not adequately implemented.

Specifically,

Your firm's SOP QA200-07.02 Vendor Audits effective date 8/19/2020, requires the performance of paper audits as part of supplier qualification. However, paper audits were not conducted for suppliers of components used in the manufacture of drug products.

- a. There was no documentation demonstrating that suppliers of components were evaluated and approved by the Quality Unit prior to use.
- b. For all component suppliers reviewed during the inspection, there was no documentation demonstrating evaluation and approval prior to use.
- c. No completed supplier questionnaires or audit documentation were available for review.
- d. There was no documentation establishing defined supplier responsibilities or quality expectations.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Aerial A. Smith, Investigator Eric Bowles, Investigator	DATE ISSUED 02/27/2026
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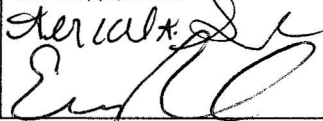
Drug Manufacturer

*** DATES OF INSPECTION**

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OF THIS PAGE

EMPLOYEE(S) SIGNATURE



EMPLOYEE(S) NAME AND TITLE (Print or Type)

Aerial A. Smith, Investigator
Eric Bowles, Investigator

DATE ISSUED

02/27/2026

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."