

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

DISTRICT ADDRESS AND PHONE NUMBER 550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513) 322-0700 Fax: (513) 679-2772	DATE(S) OF INSPECTION 4/6/2026-4/9/2026 FEI NUMBER 1519176
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Seth A. Solberg, Global Quality Vice President

FIRM NAME GOJO Industries LLC	STREET ADDRESS 3783 State Rd
CITY, STATE, ZIP CODE, COUNTRY Cuyahoga Falls, OH 44223-2603	TYPE ESTABLISHMENT INSPECTED 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

Laboratory controls do not include the establishment of scientifically sound and appropriate sampling plans designed to assure that in-process materials and drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically, your firm's sampling plan is inadequate for bulk drug product and in-process materials. For example,

- A. Bulk batch sizes range from approximately (b) (4) to (b) (4) pounds; however, sampling is limited to (b) (4) locations ((b) (4) of the tank), with (b) (4) samples collected. Your firm does not sample from the (b) (4) of the tank, and therefore does not ensure that samples are representative of the entire batch. Bulk (b) (4) batch (b) (4) consisted of approximately (b) (4) pounds of product and was sampled from only the (b) (4) of the mixing tank using a sample collection (b) (4) method). This approach does not adequately assess content uniformity throughout the batch, particularly in the (b) (4) portion of the tank. Additionally, for microbiological testing, a (b) (4) is collected from (b) (4) the (b) (4) of the tank. Your firm did not provide scientific justification for this limited sampling approach or for the reduced sample size relative to chemical and analytical testing.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Anna M Spiros, Investigator	DATE ISSUED 4/9/2026
	Anna M Spiros Investigator Signed By: 2004340890 Date Signed: 04-09-2026 17:04:19 X	

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B. In-process sampling frequency for chemical, analytical, and microbiological testing is determined by time intervals and major changes that occur during filling, but does not consider overall batch size. For example, (b) (4) (b) (4) batch # (b) (4) was filled over approximately (b) (4). During this period, your firm filled and packaged approximately (b) (4) bottles and collected only (b) (4) in-process samples for chemical, analytical, and microbiological testing. Your firm has not provided adequate scientific justification demonstrating that this sampling frequency is sufficient to ensure the batch is representative and meets established quality attributes.			
OBSERVATION 2 Drug products are not stored under appropriate conditions of temperature, humidity and light so that their identity, strength, quality, and purity are not affected. Specifically, your firm failed to adequately evaluate, test, or control returned drug products to ensure product quality. Your firm's procedure for accepting returned products does not include analytical, chemical, or microbiological testing, nor does it assess or verify the environmental or storage conditions in which the product was exposed while outside your control. For example, your firm shipped batch (b) (4) of (b) (4) on (b) (4) and (b) (4) and subsequently received a return of (b) (4) cases on 01/07/2026. During this period, the product was outside your control, and your firm has no assurance that appropriate storage conditions were maintained. Despite this, the returned product was inspected in accordance with WIS-QAM-1018, (b) (4) RGA Inspection Type Z18, effective date 3/30/22, revision 06, and released back into inventory for distribution. In 2025 your firm processed approximately 328 returned drug products (each consisting of more than (b) (4) cases) and returned these products to saleable stock			
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without sufficient control to ensure that storage conditions had been maintained or that product quality remained unaffected.

OBSERVATION 3

Equipment and utensils are not cleaned at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically, your firm's procedure for cleaning the dispensing rooms is inadequate. This procedure, WIS-OPM-1029, Dispensing and Mix General Housekeeping and Sanitation, 1/31/2025, revision 11, does not require documentation when dispensing activities occur where multiple APIs and excipients are portioned out for manufacturing drug product purposes, i.e. (b) (4) and (b) (4) (b) (4). Additionally, your firm's procedure, does not provide cleaning instructions to ensure no cross contamination among products, such as when an API is dispensed on the same day that another API or excipient is dispensed. The current procedure only requires cleaning to be performed (b) (4). On 01/06/2026 dispensing bay (b) (4) was observed with remains of apparent white powder residue on the walls, floor, and on the dust snorkel which sits above the product being weighed out. This practice could lead to cross contamination of drug products.

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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."