

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION											
DISTRICT ADDRESS AND PHONE NUMBER 466 Fernandez Juncos Avenue San Juan, PR 00901-3223 (787) 729-8500 Fax: (787) 729-6809		DATE(S) OF INSPECTION 2/17/2026-2/27/2026*									
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Dan Bigman, President		FEI NUMBER 3010222586									
FIRM NAME Gasco Industrial Corp.	STREET ADDRESS Calle A Lote 3 Rincon Indus Park										
CITY, STATE, ZIP CODE, COUNTRY Gurabo, PR 00778-2037	TYPE ESTABLISHMENT INSPECTED 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: Facilities and Equipment System											
OBSERVATION 1 The separate or defined areas and control systems necessary to prevent contamination or mix-ups are deficient. Specifically, During this follow-up inspection, I found that your firm has failed to correct deficiencies cited in December 2023 regarding inadequate cleaning validation and procedures for shared equipment used in drug product manufacturing. Your firm continues to manufacture over-the-counter (OTC) (b) (4) soap, (b) (4) (b) (4) (b) (4) and (b) (4) drug products using the same equipment utilized for manufacturing non-pharmaceutical industrial detergents and disinfectants in your facility. My review revealed the use of shared equipment with draft versions of cleaning validation protocol and procedures. The following filling operations are examples for shared equipment for manufacturing of pharmaceutical and non-pharmaceutical products. <table border="1" style="margin: 10px auto; width: 80%; border-collapse: collapse;"> <thead> <tr> <th style="padding: 5px;">Filling</th> <th style="padding: 5px;">Product</th> <th style="padding: 5px;">Lot</th> <th style="padding: 5px;">Sales Invoice</th> </tr> </thead> <tbody> <tr> <td style="height: 40px;"></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>				Filling	Product	Lot	Sales Invoice				
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Jose F Velez Investigator Signed By: 2000547088 Date Signed: 02-27-2026 14:37:53 X											

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FOOD AND DRUG ADMINISTRATION

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(787) 729-8500 Fax: (787) 729-6809

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Gasco Industrial Corp.

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Calle A Lote 3 Rincon Indus Park

CITY, STATE, ZIP CODE, COUNTRY

Gurabo, PR 00778-2037

TYPE ESTABLISHMENT INSPECTED

OTC Drug Manufacturer

Line	Number	Number
(b) (4)		

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OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Jose F Velez, Investigator
Ivis L Negron Torres, Chemist/Biologist

Jose F Velez
Investigator
Signed By: 2000547088
Date Signed: 02-27-2026
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(b) (4) Additionally, your firm has non-dedicated (b) (4) tank (b) (4), and multiple totes and hoses to prepare the bulks of (b) (4) soap, and (b) (4) drug products non-pharmaceutical detergents and sanitizers. This observation is repeated from previous inspection in December 2023.			
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,			
A. Inadequate Cleaning Controls			
Your firm has not approved cleaning procedures for the manufacturing equipment used for (b) (4) (b) (4) soap, and (b) (4) gel drug products.			
For example, cleaning procedure, KM-WI-018, Working Instruction for Cleaning and Sanitization for (b) (4) Filling lines (b) (4) and (b) (4) has not been approved. This procedure specifies that overall cleaning steps should take between (b) (4) to (b) (4). However, my review of Form KM-FO-010, Log for Cleaning and Sanitization of Production Lines, effective date 11/08/2024 found that on 02/28/2025, a major cleaning of (b) (4) was performed in (b) (4) on filling line (b) (4). This filling line was subsequently used for filling (b) (4) lots of (b) (4) into final packaging			
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containers: (b) (4) on (b) (4), (b) (4) on (b) (4), and (b) (4) on (b) (4).

Additionally, your firm has not implemented a logbook for cleaning and sanitization of filling line (b) (4), which has been used for (b) (4) filling of multiple lots of (b) (4) gel drug products, (b) (4) of (b) (4), and non-pharmaceutical products.

Furthermore, your firm does not have records to document the cleaning critical parameters and steps for any of the tanks, totes, and filling lines.

B. Inadequate (b) (4) System Design and Controls

Your firm utilizes (b) (4) as an ingredient for (b) (4) in the (b) (4) tank. Controls have not been established to ensure (b) (4) system consistently produces pharmaceutical grade (b) (4) meeting USP (b) (4) specifications and appropriate microbial quality standards. Lots of (b) (4) drug products, and (b) (4) soap are prepared in (b) (4) tanks and non-dedicated totes using (b) (4).

For example:

- The (b) (4) system has not been validated to demonstrate it consistently produces (b) (4) meeting USP (b) (4) monograph requirements and established microbial limits.
- No installation qualification (IQ), operational qualification (OQ), or performance qualification (PQ) protocols or reports were not available for the (b) (4) system.
- On February 19, 2026, I observed the (b) (4) system in an off state. You stated that the (b) (4) system is turned on only when needed for (b) (4) in the tank.
- No approved procedures exist defining shutdown protocols, startup procedures, or the conditions under which the system may be taken offline and restarted.
- (b) (4) critical operational parameters requiring monitoring and documentation have not

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been identified or established in written procedures.

- I observed your (b) (4) system design includes two potential dead legs: the first dead leg observed at the (b) (4) system outlet and the second at the (b) (4) (b) (4) tank outlet where it connects to the (b) (4).

C. Inadequate (b) (4) Quality Monitoring Program:

An established (b) (4) sampling procedure has not been implemented for the (b) (4) quality monitoring program.

The current sampling practice lacks scientific rationale and are insufficient to ensure ongoing (b) (4) quality:

- Your firm is not conducting sampling from the (b) (4) port. According to your quality technician, the (b) (4) sampling ports currently being sampled for (b) (4) (b) (4), and (b) (4). The (b) (4) that has been treated (b) (4) (b) (4).

Your firm does not have a sound sampling frequency rationale:

- According to you, there have been (b) (4) samples collected, but only one report available for review from 04/28/2025 for (b) (4) from the (b) (4) ports since the previous inspection.
- The last (b) (4) sample performed by your external laboratory contractor collected was on June 20, 2025. The (b) (4) samples were tested for (b) (4) for (b) (4) (b) (4) regulations.
- I found that the last time (b) (4) tests were conducted was in July 2024.

D. Inadequate Process Control

Your process validation program remains on draft. No equipment validation and/or cleaning validation

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have been performed. Your firm has not conducted a validation to ensure adequate (b) (4) (b) (4) and (b) (4) in the (b) (4) tank and (b) (4) tanks. There are no procedures for the bulk manufacturing of (b) (4) and (b) (4) including establishment of critical parameters and re-sampling frequencies to prevent concentration drift.

Additionally, there is no approved validation for all filling lines for the filling of (b) (4) (b) (4), drug (b) (4) gel, and (b) (4) soap. In the manufacturing batch record, there is no space to document the critical process parameters such as mixing time and speed.

This observation is repeated from the previous inspection in December 2023.

Production System

OBSERVATION 3

Drug products failing to meet established standards, specifications and quality control criteria are not rejected.

Specifically,

A. Your firm received (b) (4) USP (b) (4) lot (b) (4), on 10/06/2025. This lot of (b) (4) was used as a component in the manufacture of (b) (4) finished (b) (4) based drug products for a total of (b) (4) units released to the market. My review of the bulk lot manufacturing orders found that preparation of (b) (4) was performed using calculations based on the (b) (4) component being (b) (4) instead of the actual (b) (4) concentration. There was no modification of the ingredient volumes to compensate for the difference in (b) (4). Laboratory records for these bulk lots showed the following results and examples of finished lots

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manufactured:

Bulk Production	Bulk Lot No.	Location	pH	Refraction Index	Percentage (b) (4)	Density (g/mL)	Finished lot
(b) (4)							

Your firm's specification for (b) (4) percentage is (b) (4) to (b) (4). (b) (4) percentage results showed a declining trend from 73.33% (10/3/2025) to 65.13% (11/4/2025), with the most recent results (b) (4) specification limit of (b) (4)%. As per the laboratory technician, your firm does not perform sampling and testing for (b) (4) percentage on the finished product containers.

Additionally, the following results were outside established specifications:

- ☐ pH: Bulk lot (b) (4) (10/23/2025); Result: 9.23 (Specification: (b) (4))
- ☐ Refractive Index: Bulk lot (b) (4) (10/3/2025); Results (b) (4) (Specification: (b) (4))
- ☐ Density: Bulk lot (b) (4) (10/3/2025); Result (b) (4) g/mL (Specification: (b) (4))
- ☐ Density: Bulk lot (b) (4) (10/3/2025); Results (b) (4) g/mL (Specification: (b) (4))

Your firm did not initiate out-of-specification (OOS) investigations for these results.

B. Your firm accepted and used (b) (4) raw material that did not meet your established

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specification of (b) (4) percentage. According to the supplier certificate of analysis (COA), the following lots contained (b) (4) concentration below the minimum specification of (b) (4):

Supplier Lot	Receiving Date	COA (b) (4)	Manufacturin g Order	Finished Lots	Unit released (bottles)
(b) (4)					

Despite your specification requiring (b) (4), these out-of-specification materials were accepted and incorporated into finished (b) (4) products, resulting in the release of a total of (b) (4) bottles to the market. Additionally, the supplier's COA specifications were inconsistent and changed without documented justification. The COA specifications indicated (b) (4) for January-February 2025 then were changed to (b) (4) in August 2025. No rationale or validation for this specification change was provided.

The impact of using subpotent (b) (4) raw material on the final concentration of (b) (4) (b) (4) formulation for finished products cannot be adequately assessed due to the failure to implement finished product sampling and testing protocols.

This observation is repeated from the previous inspection in December 2023.

Quality System

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OBSERVATION 4

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,

- A. Your firm failed to have approved written procedures to execute and has not executed all the responsibilities of the quality control unit to produce drug (b) (4) gel, (b) (4) and (b) (4) I found no approved procedures for the quality and laboratory systems:
 - ☐ Annual product reviews, qualification of employees, investigations, corrective and preventive actions, stability, process validations, batch numbering system, and out of specifications (OOS) investigations.
- B. Your firm failed to follow procedure QM-PR-002, Registry Control, effective date August 2021. A total of 8 batch records of (b) (4) and (b) (4) were not available for review during the inspection.
- C. Your firm does not have a proper drug product label control. My review found that there is no established procedure for handling and securing drug product labels. On 02/17/2026, I observed the label storage area gate was open and drug product labels were not locked for authorized personnel only.
- D. Good Documentation Practices are not being followed as stated in procedure QM-PR-006, Good Documentation Practices-GDP, Effective Date: 11/16/2022. It was observed overwriting, cross-outs without initials, dates and comments, blank spaces without obliteration, entries performed in a draft notebook and then transcribed to official laboratory notebook. Also, missing operator and/or approver signature in production and quality documents such as manufacturing order and laboratory notebook.
- E. Your firm has not designated a Quality Manager to oversight the responsibilities of the quality unit. According to the organization chart, there (b) (4) laboratory quality (b) (4) who directly

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(b) (4) to you. The job description includes both bench-level duties (conducting regular analytical testing and (b) (4) sampling collection) and senior-level responsibilities such as strategic quality system oversight, procedure generation and approval, supplier qualification approval, deviation and CAPA trending, and training program development. Finished drug product release is performed by the Production Supervisor. This observation is repeated from the previous inspection in December 2023.			
OBSERVATION 5 Complaint records are deficient in that they do not include the findings of the investigation and follow-up. Specifically, Your firm failed to follow procedure MM-PR-002, Complaints Procedure, effective date 05/05/2021. My review of the complaints found that your firm kept a list of the complaints that lacked critical information including product name, lot number, root cause analysis, conclusions, and assessment of impact to other lots. Additionally, no investigations were initiated for the complaints selected during this inspection. - Complaint 2025-08-15 was initiated on 08/15/2025 after a customer reported that (b) (4) (b) (4) labeling was missing lot number and expiration date. Your firm resolved the complaint by sending (b) (4) employees to the client location to replace the deficient labels. Upon my request, you identified the affected lot as (b) (4). This lot was part of a campaign of (b) (4) lots manufactured in June 2025. - Complaint 2025-10-10 was received on 07/10/2025 after a customer found particulates inside of (b) (4) finished product containers. Your firm resolved the complaint by providing a refund and replacing the defective bottles with new (b) (4) bottles.			
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As per my request, you found the lot number related to this complaint was (b) (4) . During the inspection, (b) (4) lot (b) (4) manufacturing record could not be located. Both events show that your firm failed to investigate root causes, assess whether other lots were potentially affected and evaluate the manufacturing environment and processes for contamination and document any conclusion and corrective actions. This observation is repeated from the previous inspection in December 2023. Laboratory Control System OBSERVATION 6 Laboratory controls do not include the establishment of scientifically sound and appropriate specifications, standards, sampling plans and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling and drug products conform to appropriate standards of identity, strength, quality and purity. Specifically, A. (b) (4) Limit Test Your firm failed to have a written and validated test procedure for the determination (b) (4) in the raw materials like (b) (4) and (b) (4) . Test method used for the evaluation of (b) (4) in (b) (4) and (b) (4) has not been validated and detection of (b) (4) using non-validated instrument also has been done since January 2025 for the release of these raw materials. In addition, data collected for the linearity test done on 01/27/2025 was stored in the instrument under (b) (4) while the instrument was acquired by the firm on January 2025 as per Work Order #54636 (OT ID#6134).			
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The Gas Chromatograph Series (b) (4) (S/N (b) (4) installed in January 2025 and currently used for determination of (b) (4) in (b) (4) raw materials (i.e. (b) (4) and (b) (4)) samples was not qualified for the intended use since only (b) (4) injections of (b) (4) were executed by instrument technician but acquisition date present in chromatographic data is from May 17, 2024. (b) (4) lots of (b) (4) and (b) (4) raw materials have been released using this GC System for further manufacturing.

Your firm failed to validate excel spreadsheet used during QC laboratory testing's. The spreadsheet used during method validation for the determination of (b) (4) in (b) (4) raw materials ((b) (4) and (b) (4)) used for the calculations of sample/standard results (i.e. Linearity, System Suitability, LOD/LOQ, Sample Solutions, Spikes) has not been validated for accuracy of test results used for the release of test. There is other spreadsheet (i.e. "Analisis Detergentes 2026") that are used in the laboratory to calculate: Average, Typical error, standard deviation, sample variation, range, minimum and maximum results as well 95% of confidence. In additions, these spreadsheets are not protected for the formulas used to prevent modification/changes/deletion of data.

B. Your firm failed to collect samples from the (b) (4) raw material that was further (b) (4) through-out filling process of manufactured products (b) (4) that could be extended up to (b) (4) as confirmed by QC Laboratory Technician to ensure the product remains within specifications.

C. Your laboratory has no established test method and sampling procedure for the detection of (b) (4) in finished (b) (4) Soap products.

D. No (b) (4) test method and sampling procedure has been established for the determination of (b) (4) in the finished product (b) (4) samples after been added and adjusted the (b) (4) content to (b) (4).

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OBSERVATION 7 Laboratory records are deficient in that they do not include the initials and signature of the second person reviewing the record for accuracy. Specifically, 1) Your firm failed to implement laboratory mechanisms to prevent analysts from submitting edited or modified raw data obtained during routine analytical tests. Specifically, a) During inspection it was found that calibration record for the pH meters (#(b) (4)) used at the QC laboratory for the release of raw materials and finished products were not verified for accuracy from period of 09/Feb/26 up to 16/Feb/26 as evidence for data collected during the inspection on 02/17/26. Even though, on 02/19/26 the same record was modified by adding initials authorizing the calibration data by the firm Chief Executive Officer (CEO) that accepted the modification of record during wrap up meeting on 02/19/26. b) During review of raw data generated by Density meter (b) (4) (S/N (b) (4)) used for the evaluation of raw materials and finished products to determine specific gravity, density and (b) (4) a raw data modification was made. For example, (b) (4) (lot # (b) (4) - (b) (4) tested on 10/02/2025) and (b) (4) (lot # (b) (4) tested on 9/25/2025) it was observed that instrument test results reports were generated on 2/24/2026 while these batches were released back in 2025. 2) Failure to exercise sufficient controls over computerized system to prevent unauthorized access/changes/modification/deletion of electronic data stored. Specifically, a) Raw data presented during partial instrument installation and qualification made on January 2025 for			
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DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 466 Fernandez Juncos Avenue San Juan, PR 00901-3223 (787) 729-8500 Fax: (787) 729-6809		DATE(S) OF INSPECTION 2/17/2026-2/27/2026*	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Dan Bigman, President		FEI NUMBER 3010222586	
FIRM NAME Gasco Industrial Corp.		STREET ADDRESS Calle A Lote 3 Rincon Indus Park	
CITY, STATE, ZIP CODE, COUNTRY Gurabo, PR 00778-2037		TYPE ESTABLISHMENT INSPECTED OTC Drug Manufacturer	
the GC Series (b) (4) (S/N (b) (4)) used for the determination of (b) (4) in (b) (4) ((b) (4) and (b) (4)) raw materials was of 5/17/2024 showing lack of accuracy of the electronic record. b) Computer associated with the gas chromatograph GC Series (b) (4) (S/N (b) (4)) did not require either a username or a password to log in. It is not possible to assign actions within the system to a unique individual. Also, system lack of audit trails or controls to determine whether data has been changed/modified or deleted. c) The refractive index test results generated by (b) (4) system used for the evaluation of raw materials and manufactured products are not saved in connection with the test. The results are entered in a excel spreadsheet for evaluation against product specifications, but raw data is not stored as confirmed by QC technician.			
OBSERVATION 8 There is no written testing program designed to assess the stability characteristics of drug products. Specifically, Your firm failed to support established expiry date indicated in the product label for the manufactured products due to lack of stability program (Protocols, Specifications, Sampling Plan, etc.) to support it. a)The finished products stored in a small room does not represent stability storage conditions			
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established in the product label. b)The finished product is not stored on the same container-closure system as that in which the drug product is marketed. c)Storage conditions at the room are not monitored (i.e. No device for temperature and % relative humidity) to ensure compliance with the long-term storage conditions (b) (4) °C/(b) (4) RH) to support product shelf life in the market. d)There is no written stability program, protocols, sampling procedures for stability samples of raw materials and manufactured products to be monitored. e)Up to date there is no evaluation of manufactured products during product shelf life to support expiry date. Even more, there is no access controls for the samples stored in the room. This observation is repeated from the previous inspection in December 2023.			
OBSERVATION 9 Reserve drug product samples are not appropriately identified, representative of each lot or batch of drug product and retained and stored under conditions consistent with product labeling. Specifically, Reserve samples from representative sample lots or batches of drug products are not selected by acceptable statistical procedures and are not examined visually at least once a year for evidence of deterioration. Specifically, your firm lacked written procedures with statistical approach during reserve sample collection. Only (b) (4) collected in a (b) (4) test tube instead of product marketed			
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 466 Fernandez Juncos Avenue San Juan, PR 00901-3223 (787) 729-8500 Fax: (787) 729-6809	DATE(S) OF INSPECTION 2/17/2026-2/27/2026* FEI NUMBER 3010222586
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Dan Bigman, President

FIRM NAME Gasco Industrial Corp.	STREET ADDRESS Calle A Lote 3 Rincon Indus Park
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container closure system and it is used also for laboratory testing. There is no record of reserve samples examination for deterioration at least once a year.

OBSERVATION 10

Procedures designed to prevent objectionable microorganisms in drug products not required to be sterile are not established, written and followed.

Specifically,

Your firm has not established sampling and microbial test methods for (b) (4) Soap, and (b) (4) Gel, including the detection of Burkholderia cepacia complex (BCC) in your finished products.

OBSERVATION 11

Written calibration procedures for instruments, apparatus, gauges, and recording devices are deficient in that they do not include specific directions, schedules, limits for accuracy and precision and provisions for remedial action if limits are not met.

Specifically,

Your firm used laboratory instruments for the release of raw materials that has not been qualified.

- a. The analytical balances (#(b) (4)) used during analytical tests were not fully qualified while using a non-certified weight mass of (b) (4). No determination of weights at the operational range, no centering, etc. to ensure reliability of sample and standards weights collected from

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES
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these balances furtherly used during sample analyses for the release of raw materials and manufactured products.

- b. pH meters # (b) (4) used in the Quality Control Laboratory for the evaluation of raw materials and manufactured products were not fully calibrated. For example, the only documented calibration results are Slope % without having reference for acceptance criteria. Even more, no evidence of the pH buffers used during the Slope % determination to ensure accuracy of measurements and calibration range prior to its use.
- c. It was observed during the review of calibration record for the (b) (4) during 02/Jul/25 thru 03/Nov25 that it was not reviewed for accuracy of calibration results by a second person sign off before use for the evaluation of manufactured products and further release of batches.

Material System

OBSERVATION 12

The identity of each component of a drug product is not verified by conducting at least one test to verify the identity, using specific identity tests if they exist.

Specifically,

You firm failed to sample and perform identification testing to the components of each drug product prior to using it. The untested components received were (b) (4), lot (b) (4) and (b) (4), lot (b) (4) from suppliers to produce (b) (4) (b) (4) and (b) (4) Gel products. For (b) (4), lot (b) (4), your firm failed to provide receiving records and Certificate of Analysis during the inspection.

This observation is repeated from the previous inspection in December 2023.

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FIRM NAME Gasco Industrial Corp.		STREET ADDRESS Calle A Lote 3 Rincon Indus Park	
CITY, STATE, ZIP CODE, COUNTRY Gurabo, PR 00778-2037		TYPE ESTABLISHMENT INSPECTED OTC Drug Manufacturer	
OBSERVATION 13 Buildings used in the manufacturing, processing, packing and holding of a drug product are not maintained in a good state of repair. Specifically, During our initial walkthrough of the facilities on 02/17/2026, we observed that the facility and equipment is not maintained in a good state of repair, clean, or organized. For example: A.No sufficient space between pallets of packaging components, such as bottles and lids, causing accumulation of materials in the production area. B.The production room is exposed to the exterior because the rolling door at the loading and unloading dock, with direct access to both production and warehouse areas, was observed completely open. The filling line is approximately (b) (4) away from the rolling door. C.Non-dedicated hoses were found uncovered and lying on the floor. Two hoses were observed open and on the floor in the pharmaceutical and non-pharmaceutical production rooms, with stagnant water containing cleaner observed approximately one foot away from the hoses. Moreover, the (b) (4) hose used for the addition of (b) (4) to pharmaceutical and nonpharmaceutical products was observed uncovered and lying on the floor. D.During the warehouse visit, we observed bird drops, dead lizards, and dead flying insects in top of boxes. Some of these boxes contained components such as lids with QC approved labels. This observation is repeated from the previous inspection in December 2023.			
*DATES OF INSPECTION 2/17/2026(Tue), 2/18/2026(Wed), 2/19/2026(Thu), 2/23/2026(Mon), 2/24/2026(Tue), 2/26/2026(Thu), 2/27/2026(Fri)			
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		Jose F Velez Investigator Signed By: 2000547088 Date Signed: 02-27-2026 14:37:53 X	

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER

466 Fernandez Juncos Avenue
San Juan, PR 00901-3223
(787) 729-8500 Fax: (787) 729-6809

DATE(S) OF INSPECTION

2/17/2026-2/27/2026*

FEI NUMBER

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Dan Bigman, President

FIRM NAME

Gasco Industrial Corp.

STREET ADDRESS

Calle A Lote 3 Rincon Indus Park

CITY, STATE, ZIP CODE, COUNTRY

Gurabo, PR 00778-2037

TYPE ESTABLISHMENT INSPECTED

OTC Drug Manufacturer

X
Ivis L Negrón Torres
Chemist/Biologist
Signed By: IVIS L NEGRON TORRES -S
Date Signed: 02-27-2026 14:38:42

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OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Jose F Velez, Investigator
Ivis L Negrón Torres, Chemist/Biologist

X
Jose F Velez
Investigator
Signed By: 2000547088
Date Signed: 02-27-2026
14:37:53

DATE ISSUED

2/27/2026

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."