

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

DISTRICT ADDRESS AND PHONE NUMBER		DATE(S) OF INSPECTION
Detroit District Office 300 River Place Drive Ste 5900 Detroit, MI 482307 (313) 393-3100		*03/09/2026-03/11/2026
		FEI NUMBER
		1832669
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED		
John J. Hollandsworth, Facility Manager		
FIRM NAME	STREET ADDRESS	
Linde Industrial Gas	3076 N State Rd. 39	
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED	
La Porte, IN 46350	Medical Gas	

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.

FACILITIES AND EQUIPMENT

DURING AN INSPECTION OF YOUR FIRM, I OBSERVED:

OBSERVATION 1

Equipment shall be constructed so that surfaces that contact components, in-process materials, or medical gases shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the medical gas beyond the official or other established requirements.

Specifically,

Your firm failed to provide adequate assurance that gasket particulate does not ingress into the container closure (e.g., tank) during filling operations. We observed (b) (4) gaskets used in the filling hose to connect to the shipping containers of the trailer trucks to be cracked and fractured. Your firm has not validated that the (b) (4) installed in the filling line is effective at removing all potential gasket particulates. No studies have been conducted to provide assurance that microscopic particulates (smaller than (b) (4)) do not bypass the (b) (4) and contaminate the finished drug product.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	<i>Shanna L. Maisano</i>	SHANNA L. MAISANO, Investigator	March 11, 2026
	<i>Scott P. McBrew</i>	Scott P. McBrew, Investigator	

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OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Shannon L. Maisano
Scott D. McGrew

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

Shannon L. Maisano, Investigator
Scott D. McGrew, Investigator

DATE ISSUED

March 11, 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."