DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street Suite 7200 One Main Place, Dallas, Texas 75202 Phone: 214 253 5200 Industry Information: www.fda.gov/oc/industry	06/03/2026 - 06/04/2026
	FEI NUMBER 3001451839

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Donald R. Beets, Plant Manager

FIRM NAME	STREET ADDRESS
Nippon Sanso Matheson, Inc.	1302 Sw 112th St
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Lawton, OK 73505-9566	Medical Gas 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.

The observations noted in this Form FDA 483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1
Computerized systems are not appropriately validated to record, store, or use data in the manufacturing, processing, and holding of medical gases.

Specifically, your firm operates approximately (b) (4) analyzers used for the analysis of (b) (4) and (b) (4) manufactured on-site. Electronic source data generated by these analyzers during the loading of trailers/ trucks for outgoing shipments of (b) (4) and (b) (4) is not retained.
For example:
• Your firm failed to retain electronic source data for Analyzers (b) (4), used to test trailer/ truck contents during outgoing bulk shipment filling of (b) (4) NF, Lot #(b) (4).
• Your firm failed to retain electronic source data for Analyzer (b) (4), used to test trailer contents during outgoing bulk shipment filling of (b) (4) USP, Lot (b) (4).

OBSERVATION 2
Second person review showing that the original records have been reviewed for accuracy, completeness, and compliance with established standards is deficient.

Specifically, second-person review of Certificates of Analysis (CoAs) used to release (b) (4) and (b) (4) is deficient, in that CoAs are not reviewed against source data prior to product release to ensure accuracy of reported data, as specified in your procedure #s 40.25 and 40.24, that governs the loading of USP (b) (4) bulk trailer and NF (b) (4) bulk trailer respectively.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	OLUWASEFUNMI AGBANIGO -S Digitally signed by OLUWASEFUNMI AGBANIGO -S Date: 2026.06.04 13:26:44 -05'00'	Oluwasefunmi Agbanigo, Investigator	06/04/2026

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 judgement, 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."