

NITROGEN- nitrogen gas
Messer Gas Puerto Rico, Inc

Messer PR - Nitrogen NF Bulk Liquid -016

Certificate of Analysis – Nitrogen, NF

Customer

Vendor / Supplier

This letter is to provide you with the Certification you requested for Nitrogen, NF, Lot #. supplied to you in cylinders / vessels by our location.

These cylinders were filled in accordance with the Standard Operating Procedures utilized for the manufacture of Medical Gases. By following these procedures, our location ensures that products are safely manufactured in compliance with FDA's Current Good Manufacturing Practices (cGMP) Regulations and FDA Medical Gas Guidelines.

CAUTION: Vendor supplies this certification to customer to assist customer in ensuring compliance with 21 CFR 211.84. This certification does not eliminate customer's obligation to comply with other portions of 21 CFR 210 & 211 including but not limited to 21 CFR 211.265 (finished product testing) for cylinders and vessels filled from these supply cylinders. These cylinders are not certified for instrument calibration purposes.

Test / Requirement

NF Specification

Lot Analysis

Identification

Pass

Odor

No appreciable odor

Oxygen

< 1.0 %

Carbon Monoxide

≤10 ppm

Assay

≥ 99.0 %

The methodology being used to perform the NF Test for Assay is indicated below:

Paramagnetic Analyzer Model #

Electrochemical Analyzer Model #

These analyzers have been validated as acceptable alternatives to the official NF Gas

Chromatography
method for Nitrogen Assay. Validation study documentation is available.

Gas Chromatography

Official USP / NF method.

Supplier Signature Date

Certificate of Analysis – Nitrogen, NF

Customer

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<i>Test / Requirement</i>	<i>NF Specification</i>	<i>Lot Analysis</i>
Identification	Pass	
Odor	No appreciable odor	
Oxygen	< 1.0 %	
Carbon Monoxide	<10 ppm	
Assay	> 99.0 %	

The methodology being used to perform the NF Test for Assay is indicated below:

_____ Paramagnetic Analyzer Model # _____

_____ Electrochemical Analyzer Model # _____

These analyzers have been validated as acceptable alternatives to the official NF Gas Chromatography method for Nitrogen Assay. Validation study documentation is available.

_____ Gas Chromatography

Official USP / NF method.

Supplier Signature _____ Date _____

Product:
Nitrogen NF

Date

Facility Name

Facility Address

Lot #

NDA

205816

Batch #

NADA 141372

Final Analysis Results

Analyzer #

Test / Units

NF Specs

Analysis Results

N/A

Odor

None

ppm O₂

≤ 10,000

ppm

(Messer Spec ≤5.0)

ppm CO

≤10.0

ppm

ppm THC

N/A

ppm

ppm H₂O

N/A

ppm

ppm CO₂

N/A

ppm

ppm H₂

N/A

ppm

Assay Results

Nitrogen min %

≥99.0%

%

(Messer Spec ≥99.999%)

NT = not tested

ppm O₂ Method Used: Manufacturer / Model #:

ppm CO Method Used: Manufacturer / Model #:

These analyzers have been validated by Messer as acceptable alternatives to the official NF for Nitrogen Assay.

Validation study documentation is maintained by Messer at the corporate offices.

Analyst

Date

Quality Reviewer

Date

Should the material not be delivered to a NF customer, the material is "Not Approved for Human Drug Use."

Certificate of Analysis – Nitrogen NF

Product:
Nitrogen NF

Date			
Facility Name			
Facility Address			
Lot #		Batch #	
NDA	205816	NADA	141372

Final Analysis Results

Analyzer #	Test / Units	NF Specs	Analysis Results
N/A	Odor	None	
	ppm O2	≤ 10,000 (Messer Spec ≤5.0)	ppm
	ppm CO	≤10.0	ppm
	ppm THC	N/A	ppm
	ppm H2O	N/A	ppm
	ppm CO2	N/A	ppm
	ppm H2	N/A	ppm
Assay Results	Nitrogen min %	≥99.0% (Messer Spec ≥99.999%)	%

NT = not tested

ppm O2 Method Used: _____ Manufacturer/ Model # : _____

ppm CO Method Used: _____ Manufacturer/ Model # : _____

These analyzers have been validated by Messer as acceptable alternatives to the official NF for Nitrogen Assay. Validation study documentation is maintained by Messer at the corporate offices.

Analyst	Date

Quality Reviewer	Date

Should the material not be delivered to a NF customer, the material is “Not Approved for Human Drug Use.”

NITROGEN

nitrogen gas

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:52374-016
Route of Administration	RESPIRATORY (INHALATION)		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NITROGEN (UNII: N762921K75) (NITROGEN - UNII:N762921K75)	NITROGEN	995 mL in 1 L

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52374-016-20	25000 L in 1 TANK; Type 0: Not a Combination Product	01/01/1960	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA205816	01/01/1960	

Labeler - Messer Gas Puerto Rico, Inc (090044413)

Registrant - Messer Gas Puerto Rico, Inc (090044413)

Establishment

Name	Address	ID/FEI	Business Operations
Messer Gas Puerto Rico, Inc		833254548	api manufacture(52374-016) , manufacture(52374-016)

Revised: 11/2025

Messer Gas Puerto Rico, Inc