

NITROGEN - nitrogen gas
Capweld Inc

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

NITROGEN COMPRESSED LABEL

NITROGEN COMPRESSED NF UN 1066

CAUTION; HIGH PRESSURE GAS CAN CAUSE RAPID SUFFOCATION Store and use with adequate ventilation use equipment rated for cylinder pressure Close valve when not in use and when empty. Use in accordance with suppliers Material Safety Data Sheet.

FIRST AID: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.

Do Not Remove this Product Label



NITROGEN CERTIFICATE OF ANALYSIS

CUSTOMER _____ VENDOR / SUPPLIER _____ THIS
LETTER IS TO PROVIDE YOU WITH THE
CERTIFICATION YOU REQUESTED FOR OXYGEN USP LOT NUMBER
_____ 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.

CAUTION: VENDOR SUPPLIES THIS CERTIFICATION TO CUSTOMER TO ASSIST CUSTOMER IN ENSURING COMPLIANCE WITH 21 CFR 211.84. THIS

CERTIFICATION DOES NOT ELIMINATE CUSTOMERS OBLIGATION TO COMPLY WITH OTHER PORTIONS OF 21 CFR 210 AND 211, INCLUDING BUT NOT

LIMITED TO 21 CFR 211.165 (FINISHED PRODUCT TESTING) FOR CYLINDERS AND VESSELS FILLED FROM THESE SUPPLY CYLINDERS. THESE CYLINDERS ARE NOT CERTIFIED FOR INSTRUMENT CALIBRATION.

TEST REQUIREMENT	NF SPECIFICATION	LOT ANALYSIS
IDENTIFICATION	PASS	
ODOR	PASS	
Oxygen	LESS THAT 1.0%	
CARBON MONOXIDE	LESS THAT 0.001%	
ASSAY	GREATER THAN 99.0%	

The methodology being used to perform the USP / NF Test for Assay is indicated below: Paramagnetic Analyzer Model # _____
Electrochemical Analyzer Model # _____

_____ Gas Chromatography Official USP/NF method

Supplier Signature _____ Date _____

J 700 a2



Number	Title	Revision Number
J 700 a2	Certificate of Analysis – Nitrogen NF	1.0

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.

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 211.165 (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 # _____

_____ Gas Chromatography Official USP / NF method.

Supplier Signature _____ Date _____

GENERAL WARNINGS AND PRECAUTIONS

WARNING: Administration of nitrogen may be hazardous or contraindicated. For use only by or under the supervision of a licensed practitioner who is experienced in the use and administration of nitrogen and is familiar with the indications, effects, dosages, methods, and frequency and

duration of administration and with hazards, contraindications, and side effects and the precautions to be taken. Rx Only

NITROGEN

nitrogen gas

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:52849-200
Route of Administration	RESPIRATORY (INHALATION)		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NITROGEN (UNII: N762921K75) (NITROGEN - UNII:N762921K75)	NITROGEN	99 L in 100 L

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52849-200-01	651 L in 1 CYLINDER		
2	NDC:52849-200-02	5947 L in 1 CYLINDER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved medical gas		01/01/1952	

Labeler - Capweld Inc (033340977)

Registrant - Capweld Inc (033340977)

Establishment

Name	Address	ID/FEI	Business Operations
Capweld Inc		033340977	manufacture

Revised: 1/2010

Capweld Inc