OXYGEN - oxygen gas Norco, Inc.

OXYGEN USP COA

Truck / Trailer#



Certificate of Analysis - Oxygen USP

This letter is to provide you with the Certification for Oxygen, USP, Batch/Lot#supplied to you in a trailer lot drop off from Norco, Inc
For USP customers, by following Norco Medical Gas 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. When the USP test results below are completed and,
WHEN DELIVEDED TO A PROPERLY FDA REGISTERED USP CUSTOMER, they are intended

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

Test	USP Specification	Lot Analysis
Assay	> 99.0%	
Identification	Pass	
Odor	No appreciable odor	STATE OF THE STATE
Carbon Monoxide	≤ 0.001%	*
Carbon Dioxide	≤ 0.003%	*

^{*}Note: The USP compendium exempts facilities that manufacture Oxygen USP by the Air Liquefaction process from required testing for Carbon Dioxide and Carbon Monoxide. Our Oxygen USP is manufactured by the Air Liquefaction Process.

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

to provide a Certificate of Analysis in keeping with current FDA guidance.

Siemens Moo

This analyzer has been validated by Norco, Inc. as an acceptable alternative to the official USP Orsat Method for Oxygen Assay. Norco, Inc. maintains validation study documentation at the production location. All other tests (if applicable) performed by compendial methods.

Analysis By:	Date:
Reviewed & Released By:	Date:

Form asu_001 Revision 2 March 7, 2011

OXYGEN, COMPRESSED USP UN1072 OXYGEN 2 (R-K20) 133707R

WARNING: For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation.

For all other medical applications, **Rx only**. Uninterrupted use of high concentrations of oxygen over a long duration, without monitoring

its effect on oxygen content of arterial blood, may be harmful. Do not attempt to use on patients who have stopped breathing unless

used in conjunction with resuscitative equipment. Produced by Air Liquefaction.

DANGER: MAY CAUSE OR INTENSIFY FIRE;

OXIDIZER. CONTAINS GAS UNDER PRESSURE; MAY EXPLODE IF HEATED. Do not handle until all safety precautions have been

read and understood. Keep and store away from clothing and other combustible materials. Keep valves and fittings free from

grease and oil. Use and store only outdoors or in a well-ventilated place. In case of fire: Stop leak if safe to do so. Protect

from sunlight when ambient temperature exceeds 52 C (125 F). Use a back flow preventive device in the piping. Close valve

after each use and when empty. Use only with equipment rated for cylinder pressure. Do not open valve until connected

to equipment prepared for use. Use only equipment of compatible materials of construction. Open valve slowly.

Use only with equipment cleaned for oxygen service. Read and follow the Safety Data Sheet (SDS) before use.

CAS: 7782-44-7

DO NOT REMOVE THIS PRODUCT LABEL

Norco 1125 W. Amity Road • Boise, ID 83705 **208-336-1643**

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 D 15	C 9	M6 6
E36M 3	<u> </u>	



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OXYGEN REFRIGERATED LIQUID LABEL

REFRIGERATED LIQUID
OXYGEN
REFRIGERATED
LIQUID
USP
UN1073
OXYGEN 2 (R-K14) XXXXXX

↑ ALWAYS KEEP CONTAINER IN UPRIGHT POSITION. ↑ DO NOT CHANGE OR FORCE FIT CONNECTIONS.

	LTRS:
CONTENTS:	CU.FT

WARNING:

USP For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications. **Rx only.**

Uninterrupted use of high concentrations of oxygen over a long duration, without monitoring its effect on oxygen content of arterial blood, may be harmful. Do not attempt to use on patients who have stopped breathing unless used in conjunction with resuscitative equipment.

Produced by Air Liquefaction.

DANGER:

MAY CAUSE OR INTENSIFY FIRE; OXIDIZER.

CONTAINS REFRIGERATED GAS; MAY CAUSE CRYOGENIC

BURNS OR INJURY.

COMBUSTIBLES IN CONTACT WITH LIQUID OXYGEN MAY EXPLODE ON IGNITION OR IMPACT.

Do not handle until all safety precautions have been read and understood. Keep and store away from clothing and other combustible materials. Keep valves and fittings free from grease and oil. Use and store only outdoors or in a wellventilated place. Wear cold insulating gloves, face shield, and eve protection. In case of fire: Stop leak if safe to do so. Use a back flow preventive device in the piping. Use only with for cylinder pressure. Use only with equipment cleaned for oxygen service. DO NOT change or force fit connections. Avoid spills. Do not walk on or roll equipment over spills. Close valve after each use and when empty. Always keep container in upright position. Read and follow the Safety Data Sheet (SDS) before use.

FIRST AID: IF ON SKIN: Thaw frosted parts with lukewarm water. Do not

rub affected area. Get immediate medical advice/attention.

CAS: 7782-44-7

DO NOT REMOVE THIS PRODUCT LABEL

Norco 1125 W. Amity Road Boise, ID 83705 208-336-1643



DANGEK:

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BURNS OR INJURY.

COMBUSTIBLES IN CONTACT WITH LIQUID OXYGEN MAY EXPLODE ON IGNITION OR IMPACT.

Do not handle until all safety precautions have been read and understood. Keep and store away from clothing and other combustible materials. Keep valves and fittings free from grease and oil. Use and store only outdoors or in a wellventilated place. Wear cold insulating gloves, face shield, and eye protection. In case of fire: Stop leak if safe to do so. Use a back flow preventive device in the piping. Use only with equipment of compatible materials of construction and rated for cylinder pressure. Use only with equipment cleaned for oxygen service. DO NOT change or force fit connections. Avoid spills. Do not walk on or roll equipment over spills. Close valve after each use and when empty. Always keep container in upright position. Read and follow the Safety Data Sheet (SDS) before use.

FIRSTAID:

IF ON SKIN: Thaw frosted parts with lukewarm water. Do not rub affected area. Get immediate medical advice/attention.

CAS: 7782-44-7

DO NOT REMOVE THIS PRODUCT LABEL.



1125 W. Amity Road Boise, ID 83705



res

OXYGEN

oxygen gas

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NDC:42602-001 **Product Type HUMAN PRESCRIPTION DRUG** Item Code (Source)

RESPIRATORY (INHALATION) **Route of Administration**

Active Ingredient/Active Moiety

ı	Ingredient Name	Basis of Strength	Strength
ı	OXYGEN (UNII: S88TT14065) (OXYGEN - UNII:S88TT14065)	OXYGEN	999 L in 1000 L

Packaging

#	Item Code	Package Description	магкетіng Start Date	магкетіng Ena Date
1	NDC:42602- 001-01	7051.68 L in 1 CYLINDER; Type 0: Not a Combination Product	09/01/2008	
2	NDC:42602- 001-02	679.68 L in 1 CYLINDER; Type 0: Not a Combination Product	09/01/2008	
3	NDC:42602- 001-03	153919.2 L in 1 DEWAR; Type 0: Not a Combination Product	09/01/2008	
4	NDC:42602- 001-04	169.92 L in 1 CYLINDER; Type 0: Not a Combination Product	09/01/2008	
5	NDC:42602- 001-05	254.88 L in 1 CYLINDER; Type 0: Not a Combination Product	09/01/2008	
6	NDC:42602- 001-06	424.8 L in 1 CYLINDER; Type 0: Not a Combination Product	09/01/2008	
7	NDC:42602- 001-07	566.4 L in 1 CYLINDER; Type 0: Not a Combination Product	09/01/2008	
8	NDC:42602- 001-08	1132.80 L in 1 CYLINDER; Type 0: Not a Combination Product	09/01/2008	
9	NDC:42602- 001-09	2548.8 L in 1 CYLINDER; Type 0: Not a Combination Product	09/01/2008	
	NDC:42602- 001-10	3511.68 L in 1 CYLINDER; Type 0: Not a Combination Product	09/01/2008	
11	NDC:42602- 001-11	4361.28 L in 1 CYLINDER; Type 0: Not a Combination Product	09/01/2008	
12	NDC:42602- 001-12	7957.92 L in 1 CYLINDER; Type 0: Not a Combination Product	09/01/2008	
13	NDC:42602- 001-13	9543.84 L in 1 CYLINDER; Type 0: Not a Combination Product	09/01/2008	
14	NDC:42602- 001-14	129620.64 L in 1 DEWAR; Type 0: Not a Combination Product	09/01/2008	
13	001-15	94588.8 L in 1 DEWAR; Type 0: Not a Combination Product	09/01/2008	
	NDC:42602- 001-16	18068.16 L in 1 DEWAR; Type 0: Not a Combination Product	09/01/2008	
	NDC:42602- 001-17	26620.8 L in 1 DEWAR; Type 0: Not a Combination Product	09/01/2008	
	NDC:42602- 001-18	31831.68 L in 1 DEWAR; Type 0: Not a Combination Product	09/01/2008	05/01/2024
	NDC:42602- 001-19	35258.4 L in 1 DEWAR; Type 0: Not a Combination Product	09/01/2008	
	NDC:42602- 001-20	144304 L in 1 DEWAR; Type 0: Not a Combination Product	09/01/2008	
	NDC:42602- 001-21	176812 L in 1 DEWAR; Type 0: Not a Combination Product	09/01/2008	
22	NDC:42602- 001-22	47898 L in 1 DEWAR; Type 0: Not a Combination Product	09/01/2008	
23	NDC:42602- 001-23	35924 L in 1 DEWAR; Type 0: Not a Combination Product	09/01/2008	
24	NDC:42602- 001-24	15966 L in 1 DEWAR; Type 0: Not a Combination Product	09/01/2008	
25	NDC:42602- 001-25	7983 L in 1 DEWAR; Type 0: Not a Combination Product	09/01/2008	
26	NDC:42602- 001-26	36722 L in 1 DEWAR; Type 0: Not a Combination Product	09/01/2008	

Marketing Information					
Marketing	Application Number or Monograph	Marketing Start	Marketing End		

Category	Citation	Date	Date
NDA	NDA205820	09/01/2008	

Labeler - Norco, Inc. (043694645)

Registrant - Norco, Inc. (043694645)

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Name	Address	ID/FEI	Business Operations
Norco, Inc.		363348041	manufacture(42602-001)

Establishment

Name	Address	ID/FEI	Business Operations
Norco, Inc.		788617470	transfill(42602-001)

Establishment

Name	Address	ID/FEI	Business Operations
Norco, Inc.		962460528	transfill(42602-001), manufacture(42602-001)

Establishment

Name	Address	ID/FEI	Business Operations
Norco, Inc.		137272659	transfill(42602-001)

Establishment

Name	Address	ID/FEI	Business Operations
Norco, Inc.		806455218	transfill(42602-001)

Establishment

Name	Address	ID/FEI	Business Operations
Norco, Inc.		047109152	transfill(42602-001)

Establishment

Name	Address	ID/FEI	Business Operations
Norco, Inc.		118976116	transfill(42602-001)

Establishment

Name	Address	ID/FEI	Business Operations
Norco, Inc.		121650725	transfill(42602-001)

Establishment

Name	Address	ID/FEI	Business Operations
Norco, Inc.		102723566	transfill(42602-001)

Establishment

Name	Address	ID/FEI	Business Operations

Norco, Inc.		946853975	transfill(42602-001)
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Name	Address	ID/FEI	Business Operations
co, Inc.		055249275	transfill(42602-001)
stablishmen	t		
Name	Address	ID/FEI	Business Operations
rco, Inc.		111928342	transfill(42602-001)
stablishmen	t		
Name	Address	ID/FEI	Business Operations
rco, Inc.		018698922	transfill(42602-001)
stablishmen	t		
Name	Address	ID/FEI	Business Operations
rco, Inc.		083704353	transfill(42602-001)
tablishmen	t		
Name	Address	ID/FEI	Business Operations
co, Inc.		071401038	transfill(42602-001)
tablishmen	t		
Name	Address	ID/FEI	Business Operations
co, Inc.		946857844	transfill(42602-001)
stablishmen	t		
Name	Address	ID/FEI	Business Operations
co, Inc.		190752779	transfill(42602-001)
tablishmen	t		
Name	Address	ID/FEI	Business Operations
rco, Inc.		078368984	transfill(42602-001)
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Name rco, Inc.	Address	ID/FEI	Business Operations
CO, IIIC.		845354000	transfill(42602-001)
stablishmen			
Name	Address	ID/FEI	Business Operations
rco, Inc.		139356232	transfill(42602-001)
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Establishment			
Name	Address	ID/FEI	Business Operations
Norco, Inc.		945038586	transfill(42602-001)

Establishme	nt		
Name	Address	ID/FEI	Business Operations
Norco, Inc.		781691357	transfill(42602-001)
Establishme	nt		
Name	Address	ID/FEI	Business Operations
Norco, Inc.		181115270	transfill(42602-001)
Establishme	nt		
Name	Address	ID/FEI	Business Operations
Norco, Inc.		003202152	transfill(42602-001)
Establishme	nt		
Name	Address	ID/FEI	Business Operations
Norco, Inc.		961763211	manufacture(42602-001)
Establishme	nt		
Name	Address	ID/FEI	Business Operations
Norco, Inc.		043022300	transfill(42602-001)
Establishme	nt		
Name	Address	ID/FEI	Business Operations
Norco, Inc.		097817373	transfill(42602-001)
Establishme	nt		
Name	Address	ID/FEI	Business Operations
Norco, Inc.		130071848	transfill(42602-001)
Establishme	nt		
Name	Address	ID/FEI	Business Operations
Norco, Inc.		182023523	transfill(42602-001)
Establishme	nt		
Name	Address	ID/FEI	Business Operations
Norco, Inc.		832014042	transfill(42602-001)
Establishme	nt		
Name	Address	ID/FEI	Business Operations
Norco, Inc.		039050695	transfill(42602-001)
Establishme	nt		
Name	Address	ID/FEI	Business Operations
Norco, Inc.		034050950	transfill(42602-001)
Establishme	nt		
Name	Address	ID/FEI	Business Operations

Establishment			
Name	Address	ID/FEI	Business Operations
Norco Inc.		079208258	transfill(42602-001)

Establishment			
Name	Address	ID/FEI	Business Operations
Norco Inc.		603752429	transfill(42602-001)

Establishment			
Name	Address	ID/FEI	Business Operations
Norco Inc.		079093441	transfill(42602-001)

Establishment				
Name	Address	ID/FEI	Business Operations	
Norco Inc.		165524927	transfill(42602-001)	

Establishment				
Name	Address	ID/FEI	Business Operations	
Norco Inc.		132810735	transfill(42602-001)	

Establishment				
Name	Address	ID/FEI	Business Operations	
Norco Inc.		964889302	transfill(42602-001)	

Establishment				
Name	Address	ID/FEI	Business Operations	
Norco Inc.		966761629	transfill(42602-001)	

Establishme	ent		
Name	Address	ID/FEI	Business Operations
Norco Inc.		078578534	transfill(42602-001)

Establishment				
Name	Address	ID/FEI	Business Operations	
Norco Inc.		033960626	transfill(42602-001)	

Establishme	nt		
Name	Address	ID/FEI	Business Operations
Norco Inc.		080012315	transfill(42602-001)

Establishment			
Name	Address	ID/FEI	Business Operations
Norco Inc.		078823016	transfill(42602-001)
NOTCO IIIC.		070023010	ti alistiii(42002-001)

Establishment				
Name	Address	ID/FEI	Business Operations	
Norco Inc.		831811927	transfill(42602-001)	

Establishment			
Name	Address	ID/FEI	Business Operations
Norco Inc.		040161353	transfill(42602-001)

Establishment				
Name	Address	ID/FEI	Business Operations	
Norco Inc.		118976134	transfill(42602-001)	

Establishment			
Name	Address	ID/FEI	Business Operations
Norco Inc.		066045254	transfill(42602-001)

Establishment			
Name	Address	ID/FEI	Business Operations
Norco Inc.		081037862	transfill(42602-001)

Revised: 5/2024 Norco, Inc.