

**OXYGEN - oxygen gas**  
**Sims Welding Supply Co, 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.*

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**OXYGEN CERTIFICATE OF ANALYSIS**

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8.11 CERTIFICATE OF ANALYSIS - OXYGEN USP

CERTIFICATE OF ANALYSIS OXYGEN LIQUEFIED

CUSTOMER\_\_\_\_ DATE\_\_\_\_\_ LOT#\_\_\_\_\_ INVOICE#\_\_\_\_\_

USP MEDICAL GRADE

TEST/REQUIREMENT	NF SPECIFICATION	LOT ANALYSIS	ANALYTICAL METHOD
IDENTIFICATION SERVOMEX	PASS		PARAMAGNETISM -
ODOR	NO APPRECIABLE ODOR		ORGANOLEPTIC
CARBON DIOXIDE	LESS THAN OR EQUAL TO 0.03%	SEE NOTE	SEE NOTE
CARBON MONOXIDE	LESS THAN OR EQUAL TO 0.001%	SEE NOTE	SEE NOTE
ASSAY SERVOMEX	GREATER THAN OR EQUAL TO 99.6%		PARAMAGNETISM -

NOTE: USP/NF EXEMPTS FACILITIES THAT MANUFACTURE OXYGEN USP BY THE AIR LIQUEFACTION PROCESS FROM THE TESTS FOR CARBON DIOXIDE AND CARBON MONOXIDE. OUR OXYGEN USP IS MANUFACTURED BY THE AIR LIQUEFACTION PROCESS

THE METHODOLOGY BEING USED TO PERFORM THE USP/NF TEST FOR ASSAY IS INDICATED BELOW:

PARAMAGNETIC ANALYZER MODEL: SERVOMEX 5200

SUPPLIER SIGNATURE:\_\_\_\_\_ DATE:\_\_\_\_\_



8.11 Certificate of Analysis – Oxygen USP



Certificate of Analysis

OXYGEN, LIQUEFIED

Sims Welding Supply Co., Inc.  
18903 S. Main Street, Gardena, CA 90248  
Ph (310) 327-6651 Fx (310)217-7641

Customer: \_\_\_\_\_

Date: \_\_\_\_\_  
Lot #: \_\_\_\_\_  
Invoice #: \_\_\_\_\_

USP MEDICAL GRADE

This material was filled in accordance with our Standard Operating Procedures utilized for the manufacture of medical gases. These procedures ensure that products are safely manufactured in compliance with the FDA's Current Good Manufacturing Practices (cGMP) Regulations and FDA Medical Gas Guidelines for medical gas customers.

For non-medical gas customers, this material is "Not approved for human drug use."

Test / Requirement	NF Specification	Lot Analysis	Analytical Method
Identification	Pass		Paramagnetism – Servomex
Odor	No appreciable odor		Organoleptic
Carbon Dioxide	≤ 0.03%	*(See note)	*(See note)
Carbon Monoxide	≤ 0.001%	*(See note)	*(See note)
Assay	≥ 99.6%		Paramagnetism – Servomex

\* Note: USPINF exempts facilities that manufacture Oxygen USP by the Air Liquefaction process from the tests for Carbon Dioxide and Carbon Monoxide. Our Oxygen, USP is manufactured by the Air Liquefaction Process.

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

Paramagnetic Analyzer Model: Servomex 5200

Supplier Signature: \_\_\_\_\_ Date: \_\_\_\_\_

## WARNINGS AND PRECAUTIONS

THIS MATERIAL WAS FILLED IN ACCORDANCE WITH OUR STANDARD OPERATING PROCEDURES UTILIZED FOR THE MANUFACTURE OF MEDICAL GASES. THESE PROCEDURES ENSURE THAT PRODUCTS ARE SAFELY MANUFACTURED IN COMPLIANCE WITH THE FDA'S CURRENT GOOD MANUFACTURING PRACTICES (cGMP) REGULATIONS AND FDA MEDICAL GAS GUIDELINES FOR MEDICAL GAS CUSTOMERS. FOR NON-MEDICAL CUSTOMERS, THIS MATERIAL IS NOT APPROVED FOR HUMAN DRUG USE.

## OXYGEN

oxygen gas

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:55586-001
Route of Administration	RESPIRATORY (INHALATION)		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYGEN (UNII: S88TT14065) (OXYGEN - UNII:S88TT14065)	OXYGEN	99 L in 100 L

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55586-001-01	387367 L in 1 TANK		
2	NDC:55586-001-02	618485 L in 1 TANK		
3	NDC:55586-001-03	683589 L in 1 TANK		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved medical gas		01/01/1971	

**Labeler** - Sims Welding Supply Co, Inc. (135480783)

**Registrant** - Sims Welding Supply Co, Inc. (135480783)

**Establishment**

Name	Address	ID/FEI	Business Operations
Sims Welding Supply Co, Inc.		135480783	manufacture

Revised: 1/2010

Sims Welding Supply Co, Inc.