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.

OXYGEN CERTIFICATE OF ANALYSIS

SIMS WELDING SUPPLY QUALITY ASSURANCE PROGRAM VERSION 8 AUGUST 2007 PAGE 128

8.11 CERTIFICATE OF ANALYSIS - OXYGEN USP

CERTIFICATE OF ANALYSIS OXYGEN LIQUEFIED

CUSTOMER____DATE___LOT#____INVOICE#____

USP MEDICAL GRADE

TEST/REQUIREMENTNF SPECIFICATIONLOT ANALYSISANALYTICAL METHODIDENTIFICATIONPASSPARAMAGNETISM -

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 GREATER THAN OR EQUAL TO 99.6% PARAMAGNETISM -

SERVOMEX

SERVOMEX

ODOR

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:	

ima		renaming supply a	Version 8 August 2007 Page 128
11 Certificate of An	nalysis – Oxygen L	ISP	
<u> </u>			
SIMS SUPPLY	Certificate o	f Analysis	
Welland School			OXYGEN, LIQUEFIED
ns Welding Supply Co., Inc. 03 5. Man Street Gardens, CA 90 (310) 327-6651 Fx (310)217-7541	248		
atomer:			
		Date: Lot #	
		Invoice #:	
	USP MEDIC		
is material was filled in accor			s utilized for the manufacture of
stomers.			Gas Guidelines for medical gas
stomers.	ractices (cGMP) Regulation gas customers, this matering NF Specification		
stomens. For non-medical	ges customers, this materi	al is "Not approved for	human drug use."
stomens. For non-medical Test / Requirement	ges customers, this materi	al is "Not approved for	human drug use."
for non-medical For non-medical Test / Requirement Identification	ges customers, this materi NF Specification Pass No appreciable	al is "Not approved for	human drug use " Analytical Method Paramagnetism – Servorrex
stomers. For non-medical Test / Requirement Identification Odor	gas customers, this materi NF Specification Pass No appreciable odor	el la "Not approved for Lot Analysis	human drug use." Analytical Method Paramagnetism – Servorrex Organoleptic
for non-medical For non-medical Itest / Requirement Identification Odor Carbon Dioxide	gas customers, this material NF Specification Pass No appreciable oddr ≤ 0.03% ≤ 0.001% ≥ 99.6%	el la "Not approved for Lot Analysis *(See note) *(See note)	human drug use." Analytical Method Paramagnetism – Servornex Organoleptic *(See note) *(See note) Paramagnetism – Servornex
For non-medical Test / Requirement Identification Odor Carbon Dioxide Carbon Monoxide	gas customers, this materi NF Specification Pass No appreciatie odor ≤ 0.03% ≤ 0.001% ≥ 59.6% w USHMF scenets facilities 6	el la "Not approved for Lot Analysis * (See note) * (See note) at mandeture Organ (d	human drug use." Analytical Method Paramagnetism – Servornex Organoleptic *(See note) *(See note)
For non-medical For non-medical Identification Odor Carbon Dioxide Carbon Monoxide Assay	gas customers, this materi NF Specification Pass No appreciatie odor ≤ 0.03% ≤ 0.03% ≤ 0.001% ≥ 59.6% er: USHM# exempt facilities 6 mits for Caston Daxite are Liquefliction Process.	el la "Not approved for Lot Analysis *(See note) *(See note) *(See note) to compare US Carbon Moresult. Our On	human drug use." Analytical Method Paramagnetism – Servomex Organoleptic (See note) (See note) (See note) Paramagnetism – Servomex Paramagnetism – Servomex Paramagnetism – Servomex
For non-medical For non-medical Identification Odor Carbon Dioxide Carbon Monoxide Assay	gas customers, this material NF Specification Pass No appreciate oddr ≤ 0.03% ≤ 0.001% ≥ 99.6% Mill MC Carton Dexits an Clayerholdin Process operform the USPINE Test	el la "Not approved for Lot Analysis *(See note) *(See note) *(See note) to compare US Carbon Moresult. Our On	human drug use." Analytical Method Paramagnetism – Servomex Organoleptic (See note) (See note) (See note) Paramagnetism – Servomex Paramagnetism – Servomex Paramagnetism – Servomex
For non-medical For non-medical Identification Odor Carbon Dioxide Carbon Monoxide Assay * Net e methodology being used to	gas customers, this material NF Specification Pass No appreciate oddr ≤ 0.03% ≤ 0.001% ≥ 99.6% Mill MC Carton Dexits an Clayerholdin Process operform the USPINE Test	el la "Not approved for Lot Analysis *(See note) *(See note) *(See note) to compare US Carbon Moresult. Our On	human drug use." Analytical Method Paramagnetism – Servomex Organoleptic (See note) (See note) (See note) Paramagnetism – Servomex Paramagnetism – Servomex Paramagnetism – Servomex

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					
Ingred	lient Name	Basis of Strength	Strength		
OXYGEN (UNII: S88TT14065) (OXYGE	EN - UNII:S88TT14065)	OXYGEN	99 L in 100 L		

Pac	kaging				
#	Item Code	Package Description	Marketin	g Start Date M	farketing End Date
l NI	DC:55586-001-01	387367 L in 1 TANK			
2 NI	DC:55586-001-02	618485 L in 1 TANK			
B NI	DC:55586-001-03	683589 L in 1 TANK			
Ma	rketing Infor	mation			
	r keting Infor	mation Application Number or Monog	raph Citation	Marketing Start Date	Marketing End Date

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.