OXYGEN- oxygen gas
Aspen Air U.S., LLC

OXYGEN - 001

OXYGEN CERTIFICATE OF ANALYSIS

THIS DOCUMENT IS THE CERTIFICATE OF ANALYSIS OF OXYGEN USP LOT # _____ SUPPLIED TO YOU IN A TRAILER FROM OUR BILLINGS MONTANA LOCATION OR PICKED UP BY THE CUSTOMER LISTED ABOVE IN THEIR TRAILER. FOLLOWING THE ASPEN AIR MEDICAL GAS PROCEDURES OUR LOCATION ENSURES THAT THE OXYGEN USP PRODUCT IS MANUFACTURED IN COMPLIANCE WITH THE FDA'S CURRENT GOOD MANUFACTURING PRACTICE REGULATIONS AND THE FDA'S MEDICAL GAS GUIDELINES. THIS DOCUMENT IS INTENDED TO SERVE AS A CERTIFICATE OF ANALYSIS FOR THE OXYGEN USP WHEN THE RESULTS OF THE PRODUCT TESTING ARE ENTERED BELOW AND THE PRODUCT HAS BEEN DELIVERED TO A REGISTERED OXYGEN USP CUSTOMER. THIS DOCUMENT IS IN COMPLIANCE WITH CURRENT FDA GUIDANCE

TEST	SPECIFICATIONS	RESULTS
ASSAY	GREATER THAN 99.5%	
IDENTIFICATION	OXYGEN	
ODOR	NONE	
CARBON DIOXIDE	LESS THAN 0.03%	
CARBON MONOXIDE	LESS THAN 0.001%	

THE METHODOLOGY USED FOR PERFORMING THE USP TEST FOR ASSAY AND IDENTIFICATION IS THE PARAMAGNETIC ANALYZER MODEL # TELEDYNE 2010 MA. THIS ANALYZER HAS BEEN VALIDATED AS AN ACCEPTABLE ALTERNATIVE TO THE OFFICIAL USP METHOD FOR OXYGEN ASSAY AND IDENTIFICATION. THE VALIDATION STUDY IS AVAILABLE FOR REVIEW UPON REQUEST. ODOR TESTING WAS PERFORMED BY THE OLFACTORY METHOD. SUPPLIER SIGNATURE _____ DATE _____

NUMBER 33 110 A1 - REVISION DATE 05/01/08

FOR ALL OXYGEN USP INSTALLATIONS THE DRIVER SHALL ENSURE AND DOCUMENT THE FOLLOWING: HOSECAPS (PLUGS) IN PLACE PRIOR TO DELIVERY YES/NO, GASKETS ARE SUITABLE FOR USE OR NEW YES/NO, HOSE PURGED PRIOR TO FILLING THE VESSEL YES/NO, HOSE RECAPED (PLUGGED) FOR STORAGE YES/NO. DRIVER SIGNATURE:_____ DATE:_____

This document is the Certificate of Analysis of oxygen USP Lot # _____ supplied

☐ To you in a trailer delivery from our Billings Montana location.

☐ Picked up by the customer listed above in their trailer

Following the Aspen Air Medical Gas procedures our location ensures that the oxygen USP product is manufactured in compliance with the FDA's Current Good Manufacturing Practice regulations and the FDA's Medical Gas Guidelines. This document is intended to serve as a Certificate of Analysis for the oxygen USP when the results of the product testing are entered below and the product has been delivered to a registered oxygen USP customer. This document is in compliance with current FDA guidance.

Test	Specification	Results
Assay	≥ 99.5%	
Identification	Oxygen	
Odor	None	
Carbon Dioxide	≤ 0.03%	*
Carbon Monoxide	≤ 0.001%	*

* This product has been produced by the air liquefaction process and is exempt from these tests as stated in the USP monograph for oxygen.

The methodology used for performing the USP test for assay and identification is the paramagnetic analyzer model # Teledyne 2010 MA. This analyzer has been validated as an acceptable alternative to the official USP method for oxygen assay and identification. The validation study is available for review upon request. Odor testing was performed by the olfactory method

Supplier signature _____ Date: _____

For all oxygen USP installations the driver shall ensure and document the following:

Hose caps (plugs) in place prior to delivery	YES		No	
Gaskets are suitable for use or new	YES		No	
Hose purged prior to filling the vessel	YES		No	
Hose recapped (plugged) for storage	YES		No	

Driver signature _____ Date: _____

If this oxygen USP is **not** delivered to a properly registered user the product is "**Not** approved for human drug use".

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OXYGEN

oxygen gas

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42914-001
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:42914-001-01	10000000 L in 1 TANK; Type 0: Not a Combination Product	12/15/2007	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA205862	12/15/2007	

Labeler - Aspen Air U.S., LLC (790650449)

Registrant - Aspen Air U.S., LLC (790650449)

Establishment

Name	Address	ID/FEI	Business Operations
Aspen Air U.S., LLC		790650449	manufacture(42914-001)

Revised: 10/2024 Aspen Air U.S., LLC