

**OXYGEN- oxygen gas**  
**Roberts Oxygen Company, Inc.**

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**OXYGEN REFRIGERATED LIQUID, USP-045**

**ROBERTS OXYGEN**  
**ROCKVILLE, MARYLAND 20866**  
**TEL: (301) 948-8100**

**CERTIFICATE OF ANALYSIS**  
**OXYGEN REFRIGERATED LIQUID, USP\***  
**PRODUCED BY AIR-LIQUEFACTION PROCESS**

**TRAILER#:** \_\_\_\_\_

**DATE:** \_\_\_\_\_

**LOT#:** \_\_\_\_\_

\*USP applies only when used in a medical application or by medical customers properly registered with the FDA.

**Component Test Method Limit Result**

**Oxygen** \_\_\_\_\_ **>99.5%** \_\_\_\_\_

**Odor ORGANOLEPTIC N/D** \_\_\_\_\_

\_\_\_\_\_  
Product is identified as OXYGEN, USP through process validations, dedicated piping, and product specific connections.

Notes: \_\_\_\_\_

RELEASED BY: \_\_\_\_\_

SIGNATURE

RELEASED BY: \_\_\_\_\_

PRINTED NAME

Printed & Published by J.J. KELLER & ASSPCIATES, INC., Neenah, WI \* USP

(800) 327-6868 \*jjkeller.com \* Printer in the United States



oxygen gas

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:46123-045
<b>Route of Administration</b>	RESPIRATORY (INHALATION)		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>OXYGEN</b> (UNII: S88TT14065) (OXYGEN - UNII:S88TT14065)	OXYGEN	990 mL in 1 L

### Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:46123-045-01	1 L in 1 TANK; Type 0: Not a Combination Product	01/01/2014	

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
NDA	NDA205849	01/01/2014	

**Labeler** - Roberts Oxygen Company, Inc. (042646877)

### Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Roberts Oxygen Company, Inc.		791818008	manufacture(46123-045)

Revised: 11/2024

Roberts Oxygen Company, Inc.