

OXYGEN- oxygen gas
Praxair Mexico, S. de R.L. de C.V

Oxygen

PRAXAIR Track No: 012

Haciendo nuestro planeta mds productiva

Certificate of Analysis (COA)

PRAXAIR MEXICO S. de R.L. de C.V.

700 Via Matamoros drive, Garza Cantu

San Nicolas de los Garza, Nuevo Leon,

64550 Mexico

Oxygen USP NDA: 589381 Customer Name: Praxair
Inc - Harlingen Tx

FDA Establishment Identifier: 301258051 Praxair Number:
6010667

DUNS Number: 812953909

LIQUID OXYGEN USP

Batch Number:

OXMIS IC0917 MIS LOX 01 1026

Order: Lot Number: Shipping
Container:

98579309 OX MIS 101017 PRXM481 0053 481

Expiration date: 2018 01 09

This product described in this document meets the requirements of the **United States Pharmacopeia 40th edition, 2017**, and specifications of Praxair Mexico, S. de R.L. de C.V.

| Component | Specification | Analytical |
|------------------|--------------------------------------|----------------------|
| Result | Analytical Method¹ | Analyzer Used |

| | | |
|--------------|---------------------|-----------|
| Assay | NLT 99.5% by volume | 99.89%v/v |
| Paramagnetic | Servomex 4100 | |

| | | |
|----------------|---------------|----------|
| Identification | Positive | Positive |
| Paramagnetic | Servomex 4100 | |

Tester's Signature: XXXXXXXXXXXXXXXXXXXXXXXXXX

Reviewer's Signature: XXXXXXXXXXXXXXXXXXXXXXXXXX

Quality Assurance Reviewer

Notes:1. Liquid oxygen produced by the air liquefaction process.

- 2. Product is identified as Oxygen by way of oxygen specific paramagnetic analyzers
- 3. Product is identified as oxygen through process validation, dedicated piping and product specific CGA fittings.

Date/Time: 2017 10 10 01:26
OO/R-02-080/1-10

PRAXAIR Track No: 012
Haciendo nuestro planeta mds productive

Certificate of Analysis (COA)

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700 Via Matamoros drive, Garza Cantu
San Nicolas de los Garza, Nuevo Leon,
64550 Mexico

Oxygen USP NDA: 589381 Customer Name: Praxair Inc – Harlingen Tx
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| Component | Specification | Analytical Result | Analytical Method ^d | Analyzer Used |
|----------------|---------------------|-------------------|--------------------------------|---------------|
| Assay | NLT 99.5% by volume | 99.89%v/v | Paramagnetic | Servomex 4100 |
| Identification | Positive | Positive | Paramagnetic | Servomex 4100 |

Tester's Signature: XXXXXXXXXXXXXXXXXXXXXXX

Reviewer's Signature: XXXXXXXXXXXXXXXXXXXXXXX
Quality Assurance Reviewer

- Notes:**
- 1. Liquid oxygen produced by the air liquefaction process.
 - 2. Product is identified as Oxygen by way of oxygen specific paramagnetic analyzers
 - 3. Product is identified as oxygen through process validation, dedicated piping and product specific CGA fittings.

Date/Time: 2017 10 10 01:26 OO/R-02-080/1-10

PRAXAIR Track No:
Haciendo nuestro planeta mds productive

Certificate of Analysis (COA)

PRAXAIR MEXICO S. de R.L. de C.V.
700 Via Matamoros drive, Garza Cantu
San Nicolas de los Garza, Nuevo Leon,
64550 Mexico

Oxygen USP NDA: 210844 Customer Name:

FDA Establishment Identifier: 3004658099

Praxair Number:

DUNS Number: 812821245

LIQUID OXYGEN USP

Batch Number: _____

Order: _____ Lot Number: _____

Shipping

Container: _____

| <u>Component</u> | <u>Specification</u> | <u>Analytical</u> |
|------------------|--------------------------|----------------------|
| <u>Result</u> | <u>Analytical Method</u> | <u>Analyzer Used</u> |

Assay NLT 99.5% by volume _____%v/v

Paramagnetic Servomex 4100

Identification Positive _____

Paramagnetic Servomex 4100

Tester's Signature: _____

Reviewer's Signature: _____

Quality Assurance Reviewer

Notes:1. Liquid oxygen produced by the air liquefaction process.

2. Product is identified as Oxygen by way of oxygen specific paramagnetic analyzers

3. Product is identified as oxygen through process validation, dedicated piping and product specific CGA fittings.

Date/Time: _____
080/3-10

OO/R-02-



Haciendo nuestro planeta más productivo

Track No:

Certificate of Analysis (COA)

PRAXAIR MÉXICO S. de R. L. de C.V.
700 Vía Matamoros drive, Garza Cantú
San Nicolás de los Garza, Nuevo León,
64550 México

Oxygen USP NDA: 210844
FDA Establishment Identifier: 3004658099
DUNS Number: 812821245

Customer Name: _____

Praxair Number: _____

LIQUID OXYGEN USP

Batch Number:

Order: _____ Lot Number: _____ Shipping Container: _____

| <u>Component</u> | <u>Specification</u> | <u>Analytical Result</u> | <u>Analytical Method</u> ¹ | <u>Analyzer Used</u> |
|------------------|----------------------|--------------------------|---------------------------------------|----------------------|
| Assay | NLT 99.5 % by volume | _____ % v/v | Paramagnetic | Servomex 4100 |
| Identification | Positive | _____ | Paramagnetic | Servomex 4100 |

Tester's Signature: _____

Reviewer's Signature: _____
Quality Assurance Reviewer

- Notes:
1. Liquid oxygen produced by the air liquefaction process.
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Date/Time:

OO/R-02-080/3-10

OXYGEN

oxygen gas

Product Information

| | | | |
|--------------------------------|--------------------------|---------------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:72223-002 |
| Route of Administration | RESPIRATORY (INHALATION) | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------|
| OXYGEN (UNII: S88TT14065) (OXYGEN - UNII:S88TT14065) | OXYGEN | 990 mL in 1 L |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:72223-002-01 | 12310000 L in 1 CONTAINER; Type 0: Not a Combination Product | 06/08/2017 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| NDA | NDA210844 | 06/08/2017 | |

Labeler - Praxair Mexico, S. de R.L. de C.V (812953909)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------------|---------|-----------|------------------------|
| Praxair Mexico, S. de R.L. de C.V | | 812953909 | manufacture(72223-002) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------------|---------|-----------|------------------------|
| Praxair Mexico, S. de R.L. de C.V | | 812821245 | manufacture(72223-002) |

Revised: 11/2021

Praxair Mexico, S. de R.L. de C.V