

**NITROUS OXIDE- nitrous oxide gas**  
**Praxair Mexico, S. de R.L. de C.V**

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**Nitrous Oxide**

**NITROUS OXIDE USP LABEL**

**PRAXAIR** Praxair Mexico S. de, R.L. de C.V.  
Laboraicarlo de Costrel de Calidad de Producto  
Plasia Toluca  
Av Independence Ote No 300  
CP 50070 Toluca Ede de Mexico  
Tel (722)2358800

**Certificate of Analysis (COA)**

Customer Name: Praxair Distribution Inc.

Date: March 23 th, 2018 **COA US 0928**

Shipping Container: 63273

**Product:** Nitrous Oxide USP Medical Gas

**Pharmaceutical form:** Medicinal gas

**Purity:** 99.0 cmol/ mol Min. **Expiration Date:** March 23 th, 2020

**DUNS:** 8129539029 **FDA Establishment Identifier:** 3012518051

**Batch Number:** TCM-N20-MED-002-18

This product described in this document meets the requirements of the United States Pharmacopeia 39<sup>th</sup> edition 2016, Mexican United States Pharmacopeia, 11<sup>th</sup> edition 2014, Praxair Mexico, S. de R.L. de C.V. and Praxair Distribution, Inc.

<b>Component</b>	<b>Specification</b>	<b>Test Procedure</b>	<b>Results</b>
Nitrous Oxide Purity	Min. 99.0 cmol/moi	Gas Chromatograph	99.84 cmol/mol
Carbon Monoxide	Max. 5.0 µmol/mol	Detector tube	< 5 µmol/mol
Carbon Dioxide	Max. 300.0 µmol/mol	Detector tube	< 300 µmol/mol
Nitric Oxide	Max. 1.0 µmol/mol	Detector tube	< 1 µmol/mol
Nitrogen Dioxide	Max. 1.0 µmol/mol	Detector tube	< 1 µmol/mol
Ammonia	Max. 25.0 µmol/mol	Detector tube	< 25 µmol/mol
Halogens (Chlorine)	Max. 1.0 µmol/mol	Detector tube	< 1 µmol/mol
Moisture	Max. 100.0 ppm	Detector tube	< 100 ppm
Capacitance			
Air	Max 1.0 cmol/mol	Gas Chromatograph	0.16 cmol/mol

Identity                                      Positive                                      Gas Chromatograph                                      Positive

La concentracion esto expresada en unidades del Sistoma Internaciona La unidad  $\mu\text{mol/mol}$

Es equivalente a pormy  $\text{cmol/mol}$  es equivalente a  $\% \text{mol/mol}$ .

The concentration is expressed in units of the International System. The unit  $\mu\text{mol/mol}$  are equivalent to ppm and  $\text{cmol/mol}$  are equivalent to  $\% \text{mol/mol}$ .

**Compliance with requirements:**                                      Yes X No \_\_\_\_

Reviewer's Signature:

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QI. MYRNA VEONICA CRUZ MARTINEZ  
Quality Control Responsible.

**IMPORTANT** The information here contained it has been prepared by expert personnel of Praxair Mexico by way of orientation toward the user. The suggested analytic Techniques have demonstrated a high dependability I their results, however, the use that is given to the information it is completely user user's exclusive responsibility. This report cannot be reportability. This report cannot be reproduced without authorization of the Laboratory of Coontrol of Quality of Product of Praxair Mexidom, S. de, R.L. de C.V., Toluca Plants.

**QQ/r-08-019/1 – P0270**

## Certificate of Analysis (COA)

**Customer Name:** Praxair Distribution Inc.  
**Date:** March 23 th, 2018 **COA ID:** 0928  
**Shipping Container:** 63273

**Product:** Nitrous Oxide USP Medical Gas  
**Pharmaceutical form:** Medicinal gas  
**Purity:** 99,0 cmol / mol Min. **Expiration date:** March 23 th, 2020  
**DUNS:** 812953909 **FDA Establishment Identifier:** 3012518051

**Batch Number:** TCM-N2O-MED-002-18

The product described in this document meets the requirements of the United States Pharmacopeia 39th edition 2016, Mexican United States Pharmacopeia, 11th edition 2014, Praxair México, S. de R.L. de C.V. and Praxair Distribution Inc.

Component	Specification	Test procedure	Result
Nitrous Oxide Purity	Min. 99,0 cmol / mol	Gas Chromatograph	99.84 cmol/mol
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Moisture	Max. 100.0 ppm	Detector tube Capacitance	< 100 ppm
Air	Max. 1.0 cmol / mol	Gas Chromatograph	0.16 cmol/mol
Identity	Positive	Gas Chromatograph	Positive

La concentración está expresada en unidades del Sistema Internacional. La unidad µmol / mol es equivalente a ppm y cmol / mol es equivalente a %mol / mol.  
 The concentration is expressed in units of the International System. The unit µmol / mol are equivalent to ppm and cmol / mol are equivalent to %mol / mol.

**Compliance with requirements:** Yes  No

**Reviewer's Signature:**



**QI. MYRNA VERONICA CRUZ MARTINEZ**  
 Quality Control Responsible.

# NITROUS OXIDE

nitrous oxide gas

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:72223-001
<b>Route of Administration</b>	RESPIRATORY (INHALATION)		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NITROUS OXIDE (UNII: K50XQU1029) (NITROUS OXIDE - UNII:K50XQU1029)	NITROUS OXIDE	990 mL in 1 L

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72223-001-01	7064200 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	NDA210235	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(72223-001)

## Establishment

Name	Address	ID/FEI	Business Operations
Praxair Mexico, S. de R.L. de C.V		812821245	manufacture(72223-001)

Revised: 11/2020

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