

**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



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**Pharmaceutical form:** Medicinal gas  
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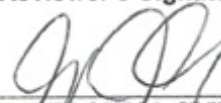
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Identity	Positive	Gas Chromatograph	Positive

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)

Revised: 10/2019

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