



## TECHNICAL SPECIFICATIONS

NAME: MEDICAL NITROGEN LIQUID/GAS, ACETI-OXIGENO, S.A.

TECHNICAL GRADE NITROGEN

### STANDARD FORMULA:

Parameters	Specification	Reference
<sup>1</sup> NITROGEN	Minimum concentration 99.999% (V/V)	CGA G-10.1
CARBON MONOXIDE	Maximum 10 ppm (V/V)	CGA G-10.1
OXYGEN	Maximum 5 ppm (V/V)	CGA G-10.1
HUMIDITY	Maximum 2 ppm (V/V)	CGA G-10.1
ODOR	None	CGA G-10.1
<sup>1</sup> NEON, ARGON & HELIUM	c.s.p. 100% (V/V)	CGA G-10.1

<sup>1</sup>Consider that traces of Neon, Argon and Helium are maintained in the nitrogen percentage.

Product Name: MEDICAL NITROGEN LIQUID/GAS, ACETI-OXIGENO, S.A.

TECHNICAL GRADE NITROGEN

Pharmaceutical Form: Gas/Liquid

Manufacturing Method: Air Liquefaction (Air Separation).

State: Cryogenic Liquid/Gas

### Applications, TECHNICAL GRADE:

- Medicinal use
- Alimentary use (Additive)

### Packed in:

- Gas:
  - Preserves in pressurized containers
  - Steel cylinders in compliance with DOT standards.
  - Valves in compliance with CGA guidelines, with non-return device.
  - Container connections must be suitable for nitrogen.
- Liquid
  - Thermos and/or stainless-steel containers.

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### Labelled

- In accordance with the sanitary registration of the provider used.
- Insert with batch number, expiration date and production.
- Each container must maintain the identification label.

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The undersigned, Authorized Public Interpreter, certifies that the present document is a translation of its original written in Spanish. Panama, November 09, 2021.

NOTE:

- It is established that for the acceptance of the raw material: Nitrogen (Liquid) and Finished Product: Nitrogen (Gas), the requirements demanded in this Standard Formula must be maintained and products outside the established ranges cannot be accepted.
- This master formula cannot be modified without the approval of the undersigned signatories.
- The handling of Liquid Nitrogen should be done with caution as it can cause serious burns to the skin. Wear your personal protective equipment: gloves resistant to cryogenic liquid, clear goggles, face shields.
- Nitrogen causes suffocation in confined spaces by displacing oxygen, so be cautious.

## References:

- COMPRESSED GAS ASSOCIATION, U.S.A.) CGA G-10.1, Commodity Specification for Nitrogen, current version.
- NITROGEN, JECFA 1999.
- PHARMACOPEA OF THE UNITED STATES OF AMERICA, USP, current version.
- FOOD Chemicals Codex

	Prepared	Revised	Approved
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Position in System:	Production Manager and HACCP Team Member	Head of Quality Control	General Manager
Signature:	(Signature)	(Signature)	(Signature)
Date:	12/04/2017	12/04/2017	12/04/2017

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