

NITROGEN- nitrogen gas
Aspen Air U.S., LLC

Nitrogen

NITROGEN CERTIFICATE OF ANALYSIS

Customer

_____ Aspen Air
_____ 1524 Lockwood Road
_____ Billings, MT

This document is the Certificate of Analysis of nitrogen NF Lot # _____ supplied
___ To you is a trailer delivery from our Billings Montana location.
___ Picked up by the customer listed above in their trailer

Following the Aspen Air Medical Gas procedures our location ensures that the nitrogen NF product is manufactured in compliance with the FDA's Current Good Manufacturing Practice regulations and the FDA's Medical Gas Guidelines. This document is intended to serve as a Certificate of Analysis for the nitrogen NF when the results of the product testing are entered below and the product has been delivered to a registered nitrogen NF customer. This document is in compliance with current FDA guidance.

| Test | Specification | Results |
|---------------------------|-------------------|---------------------------|
| Assay | ≥ 99.998% | _____ |
| Identification | Nitrogen | _____ |
| Odor | None | _____ |
| Oxygen | ≤ 10 ppm (0.001%) | _____ |
| Carbon Monoxide | ≤ 10 ppm (0.001%) | _____ |
| *Trace oxygen analyzer | AIT-21 | Model# Teledyne 3000TAEU |
| *Carbon monoxide analyzer | AIT-22 | Model# Teledyne GFC 7001E |

*This analyzer has been validated as an acceptable alternative to the official NF method. The validation study is available for review upon request. Odor Testing was performed using the olfactory method.

Supplier signature: _____ Date: _____

For all nitrogen NF installations, the driver shall ensure and document the following:

Hose caps (plugs) in place prior to delivery Yes ___ No ___

Gaskets are suitable for use or new Yes ___ No ___

Hose purged prior to filling the vessel

Yes ___ No

Hose recapped (plugged) for storage

Yes ___ No

Driver signature: _____

Date: _____

If this nitrogen NF is **not** delivered to a properly registered user the product is "**Not** approved for human drug use".

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NITROGEN

nitrogen gas

Product Information

| | | | |
|--------------------------------|--------------------------|---------------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:42914-010 |
| Route of Administration | RESPIRATORY (INHALATION) | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|-----------------|
| NITROGEN (UNII: N762921K75) (NITROGEN - UNII:N762921K75) | NITROGEN | 99 L in 100 L |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|---|-----------------------------|---------------------------|
| 1 | NDC:42914-010-01 | 11000000 L in 1 TANK; Type 0: Not a Combination Product | 12/15/2007 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| NDA | NDA205863 | 12/15/2007 | |

Labeler - Aspen Air U.S., LLC (790650449)**Registrant** - Aspen Air U.S., LLC (790650449)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|---------------------|----------------|---------------|----------------------------|
| Aspen Air U.S., LLC | | 790650449 | manufacture(42914-010) |

Revised: 10/2021

Aspen Air U.S., LLC