Linde Gas

HiQ® pharma specialty gas concept.
TRACE Pharma Nitrogen ≥ 99.5%.

HiQ® specialty gas product program

With HiQ® specialty gases from Linde Gas, the producing pharmaceutical industry is able to obtain gases that conform to agreed and internationally harmonized specifications from an approved supplier. Such pharmaceutical grade products are delivered in accordance with applicable pharmacopoeia monographs.

In order for any producer to be approved by the US Food and Drug Administration (FDA) as a manufacturer of active pharmaceutical ingredients (APIs) or pharmaceutical drug products, full compliance with current Good Manufacturing Practice (cGMP) must be assured.

In the case of gases used in production, drug producers must fulfill the requirements of US regulations 21 CFR 210 and 211 in order to assure batch uniformity and integrity of the drug product. API manufacturers must comply with ICH guideline Q7A (harmonized GMP guide created by the International Conference on Harmonisation, adopted throughout the EU, Japan and the USA). This includes requirements for the verification and documentation of purchased products as well as the demand that material must be purchased in compliance with agreed specifications.

HiQ® TRACE Pharma Nitrogen

HiQ® TRACE Pharma Nitrogen helps the producing pharmceutical industry to fulfill its needs and to reach compliance with cGMP, because the gas is traceable back to the product storage. HiQ® TRACE Pharma Nitrogen is produced according to written and documented manufacturing procedures. The gas is identified and analyzed for impurities and contaminants using qualified analysis equipment.

The specification fulfills the requirements of the European and US pharmacopoeia monographs. The analysis methods are in accordance with the same monographs or equivalent validated methods.

HiQ® TRACE Pharma Nitrogen certificate of analysis

A certificate obtained from the gas supplier saves both time and money for the pharmaceutical industry and reduces the amount of in-house gas analyses at the pharmaceutical production site. The certificate of analysis states the results and the acceptance limits of the specific analyses performed on a sample from the nitrogen batch before delivery. The information found in the certificate ensures total traceability and conformity to the pharmacopoeias.

Specification

HiQ® TRACE Pharma Nitrogen is based on and fulfills the requirements of the following current pharmacopoeia monographs:

- Nitrogen, Ph Eur
- Nitrogen, low oxygen, Ph Eur
- Nitrogen, USP/NF
- Nitrogen, JP

			Linde Gas specification	Pharmacopoeia monographs			
Components		Unit	HiQ® TRACE Pharma Nitrogen [1]	Ph Eur	Ph Eur low oxygen	USP/NF	JP
Nitrogen	N_2	%	≥ 99.5	≥ 99.5	≥ 99.5	≥ 99	≥ 99.5
Water	H_2O	ppm	≤ 5	≤ 67			
Oxygen	O_2	ppm	≤ 5	≤ 50	≤ 5	≤ 1 %	
Carbon monoxide	CO	ppm	≤ 5	≤ 5		≤ 10	
Carbon dioxide	CO_2	ppm	≤ 300	≤ 300			[3]
Argon	Ar	%	≤ 0.5		≤ 0.5		
Odor			n.d. [2]			n.d. [2]	

[1] Product version 1. The Linde product specification and version number are updated when the specifications in the pharmacopoeia monographs are changed.
[2] n.d. = not detectable
[3] Wet-chemistry test for CO_2 content.

General information

Gas type	Boiling point [1]	Heat of vaporization [1]	Specific heat capacity (15 °C)
Nitrogen	-195.8 °C	197.9 kJ/kg	1.04 kJ/kg K

[1] at 101.3 kPa

Conversion gas-liquid-mass

1 Nm^3 gaseous N_2	= 1.47 liter liquid N_2	= 1.19 kg N_2
1 liter liquid N_2	= 0.681 Nm^3 gaseous N_2	= 0.807 kg N_2
1 kg N_2	= 0.843 Nm^3 gaseous N_2	= 1.24 liter liquid N_2

1 Nm^3 = 1 m^3 at 15 °C, 101.3 kPa
Liter liquid at boiling point and 101.3 kPa

Critical values

Critical temperature	-147.05 °C
Critical pressure	33.944 bar
Critical density	0.3109 kg/l

Linde Gas - ideas become solutions.

Linde Gas

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