Linde Gas

HiQ® pharma specialty gas concept.
TRACE Pharma Synthetic Air.

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 Synthetic Air

HiQ® TRACE Pharma Synthetic Air 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 Synthetic Air 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 Synthetic Air 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 synthetic air batch before delivery. The information found in the certificate ensures total traceability and conformity to the pharmacopoeias.

Specification

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

- Air, Synthetic medicinal, Ph Eur
- Medical Air, USP

			Linde Gas specification	Pharmacopoeia monographs	
Components		Unit	HiQ® TRACE Pharma Synthetic Air [1]	Ph Eur	USP
Oxygen	O_2	%	20.0–21.7	20.0–23.6	19.5–23.5
Nitrogen	N_2		q.s.	q.s.	q.s.
Water	H_2O	ppm	≤ 67	≤ 67	[2]
Carbon dioxide	CO_2	ppm	≤ 500		≤ 500
Carbon monoxide	CO	ppm	≤ 10		≤ 10
Sulfur dioxide	SO_2	ppm	≤ 5		≤ 5
Nitric oxides	NO_x	ppm	≤ 2.5		≤ 2.5
Oil		mg/m^3	≤ 0.1		[2]
Odor			n.d. [3]		n.d. [3]

[1] Product version 1. The Linde product specification and version number are updated when the specifications in the pharmacopoeia monographs are changed.
[2] Measured as: no liquid is discernible on the mirror.
[3] n.d. = not detectable

General information

Gas type	Boiling point [1]	Specific heat capacity (15 °C)
Synthetic Air	-194 °C	1.01 kJ/kg K

[1] at 101.3 kPa

Critical values

Critical temperature	-141.7 °C
Critical pressure	36.6 bar
Critical density	0.331 kg/l

1 Nm^3 = 1 m^3 at 15 °C, 101.3 kPa

Linde Gas - ideas become solutions.

Linde Gas

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