

## HiQ® pharma specialty gas concept. TRACE Carbon Dioxide 4.0.



### 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 Carbon Dioxide 4.0

HiQ® TRACE Carbon Dioxide 4.0 helps the producing pharmaceutical industry to fulfill its needs and to reach compliance with cGMP, because the gas is traceable back to the product storage. HiQ® TRACE Carbon Dioxide 4.0 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 Carbon Dioxide 4.0 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 carbon dioxide batch before delivery. The information found in the certificate ensures total traceability and conformity to the pharmacopoeias.



### Specification

HiQ® TRACE Carbon Dioxide 4.0 is based on and fulfills the requirements of the following current pharmacopoeia monographs:

- Carbon dioxide, Ph Eur
- Carbon dioxide, USP

Components		Unit	Linde Gas specification	Pharmacopoeia monographs	
			HiQ® TRACE Carbon Dioxide 4.0 <sup>1)</sup>	Ph Eur	USP
Carbon dioxide	CO <sub>2</sub>	%	≥ 99.99	≥ 99.5	≥ 99.0
Water	H <sub>2</sub> O	ppm	≤ 10	≤ 67	≤ 150 mg/m <sup>3</sup>
Ammonia	NH <sub>3</sub>	ppm	≤ 25		≤ 25
Hydrogen sulfide	H <sub>2</sub> S	ppm	≤ 1	≤ 1	≤ 1
Nitric oxides	NO <sub>x</sub>	ppm	≤ 2	≤ 2	≤ 2.5
Carbon monoxide	CO	ppm	≤ 5	≤ 5	≤ 10
Sulfur dioxide	SO <sub>2</sub>	ppm	≤ 2	≤ 2	≤ 5
Total sulfur		ppm	≤ 1	≤ 1	
Air	N <sub>2</sub> +O <sub>2</sub>	ppm	≤ 50		

<sup>1)</sup> Product version 1. The Linde product specification and version number are updated when the specifications in the pharmacopoeia monographs are changed.

### General information

Gas type	Boiling point <sup>1)</sup>	Heat of vaporization <sup>1)</sup>	Specific heat capacity (15 °C)
Carbon dioxide	-78.4 °C	347.6 kJ/kg	0.834 kJ/kg K

<sup>1)</sup> at 101.3 kPa

### Conversion gas-liquid-mass

1 Nm <sup>3</sup> gaseous CO <sub>2</sub>	= 2.29 liter liquid CO <sub>2</sub>	= 1.87 kg CO <sub>2</sub>
1 liter liquid CO <sub>2</sub>	= 0.436 Nm <sup>3</sup> gaseous CO <sub>2</sub>	= 0.818 kg CO <sub>2</sub>
1 kg CO <sub>2</sub>	= 0.534 Nm <sup>3</sup> gaseous CO <sub>2</sub>	= 1.22 liter liquid CO <sub>2</sub>

1 Nm<sup>3</sup> = 1 m<sup>3</sup> at 15 °C, 101.3 kPa

Liter liquid at boiling point and 101.3 kPa

### Critical values

Critical temperature	31.04 °C
Critical pressure	73.815 bar
Critical density	0.4682 kg/l

HiQ® is a registered trademark of the Linde Group.

**Linde Gas-ideas become solutions.**

**Linde Gas Benelux B.V.**

Specialty Gases / HiQ Desk

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Linde Gas

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