A Member of The Linde Group | AGA

VERISEQ® pharmaceutical grade gases.
Carbon dioxide.

VERISEQ® pharmaceutical grade gases

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

To be approved by the United States (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) should be assured.

With gases used in pharmaceutical production, producers need to fulfil the requirements of US FDA Title 21 Code of Federal Regulations (CFR) Parts 210 and 211 in order to assure batch uniformity and integrity of the drug product. API manufacturers should comply with ICH guideline Q7 (harmonised GMP guide created by the International Conference on Harmonisation (ICH), adopted throughout the European Union (EU), Japan and the USA). This includes requirements for the verification and documentation of purchased products as well as the necessity for material to be purchased in compliance with agreed specifications.

VERISEQ® Carbon dioxide

VERISEQ® Carbon dioxide helps the pharmaceutical industry to fulfil its requirements and to reach compliance with cGMP, as the gas is traceable back to product storage. VERISEQ® Carbon dioxide is produced according to documented manufacturing procedures, with any impurities and contaminants identified by qualified analytical equipment, reported. The specification fulfils the requirements of the European and US pharmacopoeia monographs. The analysis methods are in accordance with the same monographs or equivalent validated methods.

Certification

The Certificate of conformity states the specified quality of the gas. The specification is guaranteed based on regular storage tank analyses. 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.

Supply options

Linde offers VERISEQ® Carbon dioxide as packaged and bulk delivery options. VERISEQ® Process Carbon dioxide fulfils the analytical and monograph requirements of the European and US Pharmacopoeias. When your requirement for traceable pharmaceutical grade carbon dioxide needs a higher purity, VERISEQ® Research Carbon dioxide with a guaranteed 4.0 purity (99.99%) is available.

Specification

VERISEQ® Carbon dioxide is based on and fulfils the requirements of the following current pharmacopoeia monographs:

→ Carbon dioxide, EP
→ Carbon dioxide, USP/NF

			Linde specifications		Pharmacopoeia monographs	
Component	Chemical formula	Unit	VERISEQ® Process Carbon dioxide[1)]	VERISEQ® Research Carbon dioxide[1)]	EP	USP/NF
Carbon dioxide	CO_2	%	≥ 99.5	≥ 99.99	≥ 99.5	≥ 99.0
Water	H_2O	ppm	≤67	≤10	≤67	≤150 mg/m³
Ammonia	NH_3	ppm	≤25	≤25		≤25
Carbon monoxide	CO	ppm	≤5	≤5	≤5	≤10
Nitric oxides	NO_x	ppm	≤2	≤2	≤2	≤2.5
Hydrogen sulphide	H_2S	ppm	≤1	≤1	≤1	≤1
Sulphur dioxide	SO_2	ppm	≤2	≤2	≤2	≤5
Total sulphur		ppm	≤1	≤1	≤1	
Air	$O_2 + N_2$	ppm		≤50		

1) The Linde product specifications are updated when the specifications in the pharmacopoeia monographs are changed.

General information

Gas type	Boiling point[2)]	Heat of vaporization[2)]	Specific heat capacity (15 °C)
Carbon dioxide	–78.4 °C	347.6 kJ/kg	0.834 kJ/kg K

2) at 101.3 kPa

Critical values

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

Conversion gas-liquid-mass

1 Nm_3 gaseous CO_2[3)]	= 2.29 litre liquid CO_2	= 1.87 kg CO_2
1 litre liquid CO_2	= 0.436 Nm^3 gaseous CO_2	= 0.818 kg CO_2
1 kg CO_2	= 0.534 Nm^3 gaseous CO_2	= 1.22 litre liquid CO_2

3) 1 Nm^3 = 1 m^3 at 15 °C, 101.3 kPa

Linde AG
Linde Gases Division, Seitnerstrasse 70, D-82049 Pullach, Germany
Phone +49.89.74 46 1661, Fax +49.89.74 46-2071, e-mail: hiq@linde-gas.com, http://hiq.linde-gas.com.

43490967 0409 – 1.1 GDP Subject to change.