THE LINDE GROUP

VERISEQ® pharmaceutical grade gases.
Oxygen.

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® Oxygen

VERISEQ® Oxygen helps the pharmaceutical industry to fulfil its requirements and to reach compliance with cGMP, as the gas is traceable back to product storage. VERISEQ® Oxygen 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 oxygen batch before delivery. The information found in the certificate ensures total traceability and conformity to the pharmacopoeias.

Supply options

Linde offers VERISEQ® Oxygen as packaged and bulk delivery options. VERISEQ® Process Oxygen fulfils the analytical and monograph requirements of the European and US Pharmacopoeias.

Specifications

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

→ Oxygen, EP
→ Oxygen, USP/NF

			Linde specifications	Pharmacopoeia monographs	
Component	Chemical formula	Unit	VERISEQ® Process Oxygen[1)]	EP	USP/NF
Oxygen	O_2	%	≥ 99.5	≥ 99.5	≥ 99.0
Water	H_2O	ppm	≤67	≤67	
Carbon monoxide	CO	ppm	≤5	≤5	≤10[2)]
Carbon dioxide	CO_2	ppm	≤300	≤300	≤300[2)]
Odour			n.d.[3)]		n.d.[3)]

1) The Linde product specification is updated when the specifications in the pharmacopoeia monographs are changed.
2) Oxygen that is produced by the air-liquefaction process is exempt from the requirements of the tests for carbon dioxide and carbon monoxide.
3) n.d. = not detectable.

General information

Gas type	Boiling point[4)]	Heat of vaporization[4)]	Specific heat capacity (15 °C)
Oxygen	–182.98 °C	213.3 kJ/kg	0.916 kJ/kg K

4) at 101.3 kPa

Critical values

Critical temperature	Critical pressure	Critical density
–118.57 °C	50.430 bar	0.436 kg/l

Conversion gas-liquid-mass

1 Nm^3 gaseous O_2[5)]	= 1.19 litre liquid O_2	= 1.36 kg O_2
1 litre liquid O_2	= 0.842 Nm^3 gaseous O_2	= 1.14 kg O_2
1 kg O_2	= 0.738 Nm^3 gaseous O_2	= 0.876 litre liquid O_2

5) 1 Nm^3 = 1 m^3 at 15 °C, 101.3 kPa

HiQ®

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