A Member of The Linde Group | AGA

VERISEQ® pharmaceutical grade gases.
Synthetic air.

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® Synthetic air

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

Supply options

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

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Specification

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

→ Air, Synthetic medicinal, EP
→ Medical air, USP/NF

			Linde specifications	Pharmacopoeia monographs	
Component	Chemical formula	Unit	VERISEQ® Process Synthetic air[1)]	EP	USP/NF
Oxygen	O_2	%	20.0 - 21.7	20.0 - 23.6[2)]	19.5 - 23.5
Nitrogen	N_2		q.s.	q.s.	q.s.
Water	H_2O	ppm	≤ 67	≤ 67	n.d.[3, 4)]
Carbon dioxide	CO_2	ppm	≤ 500		≤ 500
Carbon monoxide	CO	ppm	≤ 10		≤ 10
Nitric oxide	$NO + NO_2$	ppm	≤ 2.5		≤ 2.5
Sulphur dioxide	SO_2	ppm	≤ 5		≤ 5
Oil		mg/m^3	≤ 0.1		n.d.[3, 4)]
Odour			n.d.[4)]		n.d.[4)]

1) The Linde product specification is updated when the specifications in the pharmacopoeia monographs are changed
2) Content: 95.0 per cent to 105.0 per cent of the nominal value which is between 21.0 per cent V/V to 22.5 per cent V/V of oxygen (O_2).
3) Measured as: no liquid is discernible on the mirror.
4) n.d. = not detectable

General information

Gas type	Boiling point[5)]	Specific heat capacity (15 °C)
Synthetic air	-194.3 °C	1.01 kJ/kg K

5) at 101.3 kPa

Critical values

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

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