A Member of The Linde Group | AGA

VERISEQ® pharmaceutical grade gases.
Argon.

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® Argon

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

Supply options

Linde offers VERISEQ® Argon as packaged and bulk delivery options. VERISEQ® Process Argon fulfils the analytical and monograph requirements of the European Pharmacopoeia.

Specification

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

→ Argon, EP

			Linde specifications	Pharmacopoeia monographs
Component	Chemical formula	Unit	VERISEQ® Process Argon[1)]	EP
Argon	Ar	%	> 99.998	> 99.995[2)]
Water	H_2O	ppm	<5	<10.0
Oxygen	O_2	ppm	<5	<5.0
Nitrogen	N_2	ppm	<10	[3)]
Methane	CH_4	ppm	<1	[3)]

1) The Linde product specification is updated when the specifications in the pharmacopoeia monographs are changed.
2) Content: minimum 99.995 per cent V/V of argon, calculated by deduction of the sum of impurities found when performing the test for impurities and the water content.
3) Total: maximum 0.0040 per cent of the sum of the areas of all peaks (40.0 ppm V/V). Including oxygen.

General information

Gas type	Boiling point[4)]	Heat of vaporization[4)]	Specific heat capacity (15 °C)
Argon	–185.87 °C	161.2 kJ/kg	0.52 kJ/kg K

4) at 101.3 kPa

Critical values

Critical temperature	Critical pressure	Critical density
–122.29 °C	48.981 bar	0.5356 kg/l

Conversion gas-liquid-mass

1 Nm^3 gaseous Ar[5)]	= 1.21 litre liquid Ar	= 1.69 kg Ar
1 litre liquid Ar	= 0.825 Nm^3 gaseous Ar	= 1.39 kg Ar
1 kg Ar	= 0.591 Nm^3 gaseous Ar	= 0.717 litre liquid Ar

5) 1 Nm^3 = 1 m^3 at 15 °C, 101.3 kPa

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