THE LINDE GROUP

VERISEQ® pharmaceutical gas concept.
Liquid carbon dioxide.

Quality assured gas solution for the pharmaceutical industry

VERISEQ® pharmaceutical gas concept, PGC

By turning to VERISEQ® PGC gases, the producing pharmaceutical industry will be able to obtain industrial 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 FDA as a manufacturer of active pharmaceutical ingredients (APIs) or pharmaceutical drug products, full compliance with cGMP must be assured.

In the case of industrial gases used in production, drug producers must fulfill the requirements of U.S. regulations 21 CFR 210 and 211, in order to assure batch uniformity and integrity of the drug product. API manufacturers must comply with ICH guidelines Q7A (harmonized GMP guide created by the International Conference of Harmonisation, adopted throughout the EU, Japan and the U.S.A). This includes requirements about verification and documentation of purchased products as well as the demands that material be purchased against an agreed specification.

VERISEQ® liquid carbon dioxide

VERISEQ® liquid carbon dioxide (LIC) can be used to fulfill the needs of the producing pharmaceutical industry in reaching compliance with cGMP. VERISEQ® LIC is produced according to written and documented manufacturing procedures and 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.

VERISEQ® LIC will also support the pharmaceutical segment in complying with cGMP, since the gas is traceable back to the product storage.

A certificate obtained from the gas supplier saves both time and money for the pharmaceutical industry and reduces the in-house amount of analyses of the gas at the pharmaceutical production site.

Supply option

To ensure traceability and conformity to the Pharmacopoeias, Linde offers the following supply option:

VERISEQ® LIC – Certificate of analysis

The Certificate of analysis states the results and the acceptance limits of the specific analyses performed on a sample from the liquid carbon dioxide batch before delivery.
The information found in the certificate ensures total traceability.

Specification

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

- → Carbon dioxide, EP (Ph.Eur. 4, 01/2002:0375)
- → Carbon dioxide, USP/NF (USP26/NF21)

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

1) The Linde product specifications are updated when the specifications in the pharmacopoeia monographs are changed.
2) Hydrogen sulfide and sulfur dioxide are analyzed separately – the sum of both is not exceeding 1 ppm.

Our experts are available for consulting.

Linde Gas - ideas become solutions.

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