Linde Gas

VERISEQ® pharmaceutical gas concept.
Liquid nitrogen.

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 CMP guide created by the International Conference on Harmonisation, adopted throughout the EU, Japan and the U.S.A.). This includes requirements about the verification and documentation of purchased products as well as the demands that material be purchased against agreed specifications.

VERISEQ® liquid nitrogen

VERISEQ liquid nitrogen (LIN) can be used to fulfill the needs of the producing pharmaceutical industry in reaching this compliance with cGMP. VERISEQ LIN is produced according to written and documented manufacturing procedures. The gas is identified and analyzed for impurities and contaminants using qualified analysis equipment.
The specification fulfills the monograph requirements of the European, U.S. and Japanese Pharmacopoeia monographs. The analysis methods are in accordance with the same monographs, or equivalent validated methods.
VERISEQ LIN 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® LIN Certificate of analyses

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

Specification

VERISEQ LIN is based on, and the specification fulfills the requirements of, the following Pharmacopoeia monographs:

- Nitrogen, Ph.Eur.
- Nitrogen, low-oxygen
- Nitrogen, USP
- Nitrogen, JP

	Linde Specification	Pharmacopoeia monographs			
	VERISEQ LIN [1]	Ph.Eur.	Ph.Eur. low-oxygen	USP	JP
Nitrogen	min. 99.5 %	min. 99.5%	min. 99.5%	min. 99%	min. 99.5%
Water	max. 5 ppm	max. 67 ppm	-	-	-
Oxygen	max. 5 ppm	max. 50 ppm	max. 5 ppm	max. 1%	-
Carbon monoxide	max. 5 ppm	max. 5 ppm	-	max. 10 ppm	-
Carbon dioxide	max. 300 ppm	max. 300 ppm	-	-	[2]
Argon	max. 0.5 %	-	max. 0.5%	-	-
Odor	none	-	-	none	-

[1] Product version 1. The specification and version number are updated when the Pharmacopoeia monographs are updated.

[2] Wet-chemistry test for CO_2 content.

Our experts are available for consultation.

Linde Gas - ideas become solutions.

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