

Certified Compliance



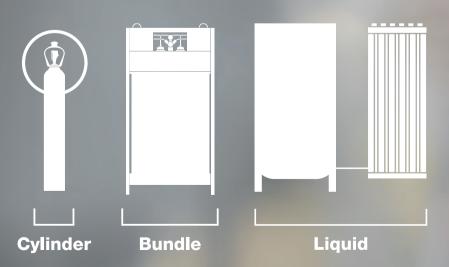
Reliable solutions for a challenging marketplace

Air Liquide excels in the delivery of safe and valuable gas solutions to meet the demands of our pharmaceutical and biotechnology customers' processes. We know that the need for patient safety means that this industry is highly regulated, resulting in strict quality assurance, mandatory traceability and a need for process control.

Our end-to-end services have enhanced our reputation as a reliable supplier to world-class pharmaceutical and biotechnology companies around the globe. Our dedicated range of pharmaceutical grade gases, **PHARGALIS™**, meets the dual need for high performance and compliance with regulatory standards.

A supply mode adapted to your needs

PHARGALIS™ products are available in cylinders, bundles or in liquid form according to your needs. Whatever your consumption, we provide our gases with the best supply mode ensuring quality, consistency and ease of use.









EXCiPACT™ CERTIFIED

PHARGALIS™ gases are certified compliant to the Good Manufacturing and Distribution Practices for pharmaceutical excipients: for a safe, reliable, and transparent pharmaceutical supply chain.

PHARGALIS™ products for peace of mind



Compliance

PHARGALIS™ products comply with the three major pharmacopoeias: USP-NF, Ph. Eur. and JP, with respect to both defined specifications and analytical methods. Our gases are traceable and delivered with certificates of analysis and conformity. They are produced and delivered according to the Good Manufacturing and Distribution Practices (GMPs and GDPs) for excipients (joint IPEC-PQG GMP and GDP Guides and EXCIPACT™ Standard for pharmaceutical excipients*).



Convenience

At Air Liquide everything is done to lighten your quality assurance burden. By providing certificates of analysis and conformity, we help our customers reduce analytical costs and gain time in the raw materials reception steps, while improving the efficiency of the risk management processes.

The **EXCIPACT™** certification brings you value through cost savings by reducing the audit load without sacrificing quality*.



Reliability

We understand how critical gases are for your processes and the impact they have on the quality and compliance of your production. This is why logistics performance is of the utmost importance to Air Liquide. With remote monitoring solutions, automatic supply according to your consumption level and strict management of product sources and back-ups, our customers can count on a reliable gas supply, supported by Air Liquide's extensive production and distribution networks.

 $^{^{\}star}$ applies exclusively to countries having an EXCiPACT certification

Our complete offer of pharmaceutical grade gases

Conceived and intended for the manufacture of Active Pharmaceutical Ingredients (APIs) and drug products, our gases are traceable and delivered with certificates of analysis and conformity. Engineered with a focus on Good Manufacturing Practices (GMPs) for excipients, PHARGALIS™ products also comply with the three major pharmacopoeias: USP-NF, Ph. Eur. and JP.

1

PHARGALIS™ 1 Nitrogen

PHARGALIS™ 1 is widely used at all steps of inerting in production and packaging processes. Above all, our solutions help to preserve the quality of active ingredients and drugs, allowing our customers to more easily eliminate oxidation and prevent microbiological contamination of their products. Nitrogen can also be used to strip the excess of CO_2 released by living organisms and which may affect the productivity of biomanufacturing processes. In freeze drying processes, **PHARGALIS™** 1 is used inside the chamber, to control the vacuum phase.

2

PHARGALIS[™] 2 Carbon dioxide

Liquid drug products are produced in batches before they are packaged in vials, ampoules, prefilled syringes, bags or bottles. Batch pH is a critical parameter that needs to be adjusted and carbon dioxide, as a weak acid, is the ideal answer to such need. Carbon dioxide is also very important for small and large scale biomanufacturing processes, in incubators and bioreactors, where it helps create optimum conditions for cell growth.

3

PHARGALIS™ 3 Oxygen

The biopharmaceutical industry manufactures complex drugs through the use of living organisms (cells, bacteria, yeast etc). These organisms are grown in fermenters and bioreactors of different sizes and types, under strictly controlled conditions. A mixture of air and pure oxygen is sparged through the cell culture media to provide replenishment of oxygen during cell growth, in order to improve production yields.

6

PHARGALIS[™] 6 Argon

In certain processes, nitrogen is not effective enough in creating a protective atmosphere for intermediate or final products. For very sensitive and fragile pharmaceutical products, **PHARGALIS™** 6 is the appropriate solution, as heavier argon molecules provide a better answer for inerting in production and packaging processes, as well as for tank blanketing needs.

Air Liquide's Industrial Merchant Business Line delivers industrial gases and innovative solutions, including application technologies, equipment and services. From independent professionals to large industrial companies, our 33,500 employees serve over 2 million customers daily across 75 countries. They use their unmatched business and technical capabilities to develop gas solutions that boost the performance of industries and help them to increase product quality, unlock greater competitiveness and minimize the environmental footprint of their manufacturing processes.

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