

Pharma grade gases

For Quality, Conformity, Traceability and Peace of Mind

➤ **Quality**

➤ **Conformity**

➤ **Traceability**

➤ **Peace of Mind**

➤ **Pharmaceutical applications demand complete reliability**

- **100% compliance with regulations**
- **Full traceability to raw material data**
- **Unique inspection lot number**
- **Reliable and cost effective sourcing of gases for API**

The Pharma grade range of gases developed by Air Products is designed for use in pharmaceutical, cosmetic and veterinary industries where quality and traceability are of utmost importance. They can be used either for research, development, production or analysis.

For over 40 years, Air Products' specialty gas business has been driven by a single, critical objective: to help you achieve consistently reliable performance in both analytical and process applications. Pharma grade gases are one more innovation towards this goal.



Conformity

➤ **Compliance with EU directives**

Pharma grade gases are compliant with the requirements of European directives 2001/83/EC and 2001/82/EC; as amended by Directives 2004/27/EC and 2004/28/EC; directives relating to use and quality of Active Product Ingredients (API). Pharma grade gases can therefore be used by pharmaceutical, cosmetic, veterinary, biotechnology or other industries to produce API's and pharmaceuticals, all with complete peace of mind.

➤ **Conformity to European Pharmacopoeia and GMP part II**

Air Products' production and analytical methods, as well as storage and distribution processes, are carefully defined and documented to guarantee full compliance to European Pharmacopoeia (EP) and GMP (Good Manufacturing Practice) part II. For example, Air Products uses the exact analytical methods and analytical equipment specified in the corresponding monograph of the European Pharmacopoeia, certificates are signed by a qualified person, and the production process and analytical system are fully validated.

Specifications

	Compliance with European Pharmacopoeia						
	Nitrogen PHARMA GRADE	Nitrogen, Monograph 01/2005:1247	Nitrogen Low oxygen Monograph 01/2005:1685	Oxygen PHARMA GRADE	Oxygen Monograph 2000:0417	Carbon Dioxide PHARMA GRADE	Carbon Dioxide Monograph 01/2005:0375
Purity	> 99.9992%	✓	✓	> 99.995%	✓	> 99.995%	✓
CO ₂	< 1 ppm	✓	✓	< 1 ppm	✓		
CO	< 1 ppm	✓	✓	< 1 ppm	✓	< 2 ppm	✓
O ₂	< 3 ppm	✓	✓				
H ₂ O	< 2 ppm	✓	✓	< 5 ppm	✓	< 7 ppm	✓
NO _x						< 2 ppm	✓
Total sulphur						< 1 ppm	✓

Quality and certification

Pharma grade gases are delivered with traceable Certificates of Analysis as standard. These are fully compliant with the monographs of the European, US and Japanese Pharmacopoeias, thus guaranteeing traceability.

Traceability

Full traceability of raw materials, production data and actual analytical values is guaranteed through a unique identifier number, allocated to each delivery. This number is called an inspection lot number, which allows tracking of the Certificate of Analysis on-line via Air Products' APDirect® internet service. To register for APDirect® online services, please go to www.airproducts.com/APDirect

Peace of Mind

The quality, conformity and traceability features of our Pharma grade gases will allow you to concentrate on your business while Air Products takes care of your gas supply. By using Pharma grade gases from Air Products, you will save time and money: approval processes for pharmaceuticals will be facilitated, internal quality control processes will be optimised, and long supplier approval processes will be avoided. Pharma grade gases are available for N₂, O₂ and CO₂. They are used in a variety of pharmaceutical processes including inerting (blanketing), packaging, cell culture and for use as propellants.

Certification

Unique inspection lot number for traceability

Analytical methods conform to European Pharmacopoeia

Analytical results

Signature of qualified person

Conformance to European directives, GMP part II and Pharmacopoeias

LOWER LIMIT	UPPER LIMIT	NOMINAL VALUE	ACTUAL VALUE	UNIT	EXPANDED UNCERT.	NO REPS.	STD DEV.	PHASE	ANALYTICAL METHOD
TOTAL PURITY									
			99.9992	%V					C
Nitrogen									
			Positive Assay						B
			0.9	ppm mo ± 2%rel					B
			0.9	ppm mo ± 2%rel					B
			< 2.0	ppm mo ± 1%rel					B
			1.8	ppm mo ± 1%rel					B

Mode of supply:

Pharma grade is available in packs or cylinders to answer the needs of low and medium volume users. Both packages are equipped with RPV valves to guarantee consistency of quality. For customers requiring larger volumes, Pharma grade gases are also available in our CryoEase® service and in bulk delivery.



Pharma grade gas cylinders: for low and medium volume users



CryoEase® service: a cost-effective and convenient choice for customers using as few as 10 large cylinders per month of a single product



Bulk delivery: for large volume users

United Kingdom
 Air Products PLC
 2 Millennium Gate, Westmere Drive
 Crewe CW1 6AP
 Tel +44 (0)845 777 8800
 Fax +44(0)1270 614170
 Email getgas@airproducts.com

Ireland
 Air Products Ireland Ltd.
 Unit 950 Western Industrial Estate
 Killeen Road
 Dublin 12
 Tel 01 463 4200
 Email ordergas@airproducts.com

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