

Frequently Asked Questions about Pharma grade

Q: What is the difference between Pharma grade gases and standard grade gases?

A: Pharma grade gases are produced in accordance with GMP part II; detailing production and analytical process requirements as well as documentation. Their specifications are compliant with European Pharmacopoeia, and are fully traceable to raw material data, production data and cylinder data. Standard grade gases are produced following ISO 9001 procedures against internal quality specifications.

Q: What makes Pharma grade gas from Air Products different to Pharma grade from your competitors?

A: Air Products is producing Pharma grade gas on a site which complies 100 % with GMP part II, whereas others refer to the “spirit” of Good Manufacturing Practice. This guarantees that the API (SM) which you receive from Air Products has a validated and traceable production process. Air Products guarantees full traceability of your gas to raw material data, reducing your in-house control. As a standard you will receive a Certificate of Analysis which allows you to eliminate your in-house analysis following verification of the supply by Air Products.

Q: Why is Air Products supplying such a high purity grade of Pharma gas? Pharmacopoeia doesn't require this.

A: Most pharmaceutical companies are requesting higher purity specifications than specified by the corresponding monograph of the European Pharmacopoeia (EP), they want to be absolutely sure that no impurities from the gas are entering the API. Air Products has therefore chosen to supply you a better quality product within the requirements of the EP. Thanks to the guarantee and traceability we provide, your supplier qualification process will be reduced and your in-house controls can be reduced.

Q: Does Air Products supply a Certificate of Analysis?

A: Yes. Air Products is supplying a Certificate of Analysis which details analytical results and methods used, compliant with the monographs of the European Pharmacopoeia. It contains a unique identifier, a 12 digit inspection lot number, which guarantees full traceability of your product. Pharma grade gases are produced in batch under specific controlled conditions and through validated processes. For cylinder customers: analytical data are stored in process for the batch of cylinders to which your cylinder belongs. Thanks to the controls we ensure that every cylinder in a batch has the same specifications within specified limits. A batch certificate assures you that every cylinder within the batch has the same impurity levels.

Q: How is Air Products ensuring traceability?

A: Traceability starts at receipt of the raw material on the production site. Following filling, packages are analysed and analysis data are collected and stored automatically. All data is linked throughout the production chain via a 12 digit code, called an inspection lot number. This unique number can be found on the certificate and on the cylinder shoulder, and it allows you to go on-line and find your certificate. Through Air Products' APDirect® customer portal, you can access your certificate when typing in this inspection lot number. The APDirect® customer portal allows you to access information about your account on-line, including (but not limited to) certificates. To register for access, please go to www.airproducts.com/APDirect



Q: Air Products is saying that raw material control can be reduced by using their Pharma grade gases. Can you clarify that?

A: Air Products is producing in compliance with the requirements of GMP part II, which guarantees a fully documented process, from raw material to finished goods, including production, analysis and warranties. It also means that Air Products sites can be audited for compliance with GMP part II and European Pharmacopoeia. Therefore you don't have to perform additional supplier qualification. By using our fully traceable gases you can reduce in-house control of your gas used.

Q: How do you ensure that Pharma grade cylinders are not contaminated by other customers?

A: Air Products has installed a Residual Pressure valve, which contains a check valve that prevents back contamination at another customer's site, on all Pharma packages.

Q: Which are the different modes of supply for Pharma grade gases from Air Products?

A: Air Products has Pharma grade gases in liquid bulk and packaged gas form, either in a liquid storage tank at your site, or in cylinders or packs to suit all kinds of needs.

Q: How do I recognise a Pharma grade product?

A: Air Products has labelled its Pharma grade product with a clear label mentioning Pharma grade on the cylinder body. Each product also has a unique number, called PR code, which is attached to the cylinder shoulder, and contains the generic description of the product

United Kingdom

Air Products PLC
2 Millennium Gate, Westmere Drive
Crewe CW1 6AP
Tel 0800 389 0202
Fax +44(0)1932 258502
Email apukinfo@airproducts.com

Ireland

Air Products Ireland Ltd.
Unit 950, Western Industrial Estate
Killeen Road, Dublin 12
Tel 1800 99 50 29
Fax +44(0)1932 258502
Email ieinfo@airproducts.com

tell me more
www.airproducts.ie
www.airproducts.co.uk