



## HiQ<sup>®</sup> specialty gas analysis services. Complying with the pharmacopoeias.



### Regular analysis, reliable production

Safety, documentation, and reliability. These are just some of the demands of today's pharmaceutical industry. Analysis services from Linde are specially developed for manufacturers of pharmaceuticals and active pharmaceutical ingredients (APIs) who use gas distribution systems in their production processes.

### Meeting GMP requirements

Manufacturers of pharmaceuticals and APIs set very high standards for safety and quality. This is also reflected in the standards set for gases and their distribution systems. To verify the contents of gas systems at factories operating under good manufacturing practice (GMP) requirements, a complete gas analysis should be carried out at least once a year. This is especially important where the gas comes into contact with the finished products.

### Regular sampling

Sampling the gas system can either involve Linde personnel regularly taking gas samples from the factory's gas system, or Linde sending sample cylinders directly to you for your own sample retrieval. Sampling is carried out in accordance with set routines. The gas sample is transferred into a special cylinder that has been designed for optimal gas testing.

The gas sample can either be taken at the external liquid gas storage tank, or at a critical point of use in the production facility, i.e. where the gas is used and comes into contact with the product. Even where the whole gas system is qualified, Linde can help with testing and analysis.

### Certified results

The gas sample is sent to one of our specialty gas laboratories for analysis. These laboratories can carry out both standardized analysis in accordance with the requirements of European and US pharmacopoeias, and completely unique gas analysis by arrangement. Our analysis equipment is qualified to comply with the requirements of the pharmacopoeias. The results are summarized in a certified report of analysis, assuring complete documentation.

### A valuable resource, also for hospitals

Gases are used in most of the steps within the manufacture of APIs and pharmaceuticals, including research and development, production, and quality control. Our understanding of the production of pharmaceuticals and formulation technology makes us a resource to be used for every aspect of your gas needs. Analysis services from Linde are also valuable to hospitals that have to adhere to the European pharmacopoeia monograph for medical compressed air.

**HiQ® specialty gases concept**

The HiQ® specialty gases concept from Linde gives you peace of mind with a wide range of specialty gas products, equipment, and services. Thanks to our innovative thinking, optimized logistics, and analytical expertise, you can worry less about your gas supply and focus more on what really matters: your work.

**Specifications**

Components		Unit	Nitrogen	Oxygen	Carbon dioxide	Synthetic air	Compressed air
Nitrogen ID	N <sub>2</sub>		ok				
Nitrogen assay	N <sub>2</sub>	vol-%	≥ 99.5				
Nitrogen	N <sub>2</sub>					q.s.	q.s.
Oxygen ID	O <sub>2</sub>			ok			
Oxygen assay	O <sub>2</sub>	vol-%		≥ 99.5		20.0–21.7	20.4–21.4
Oxygen	O <sub>2</sub>	vol-ppm	≤ 5				
Carbon dioxide ID	CO <sub>2</sub>				ok		
Carbon dioxide assay	CO <sub>2</sub>	vol-%			≥ 99.5		
Water	H <sub>2</sub> O	vol-ppm	≤ 5	≤ 67	≤ 67	≤ 67	≤ 67
Carbon dioxide	CO <sub>2</sub>	vol-ppm	≤ 300	≤ 300		≤ 500	≤ 500
Carbon monoxide	CO	vol-ppm	≤ 5	≤ 5	≤ 5	≤ 10	≤ 5
Argon	Ar	vol-%	≤ 0.5				
Ammonia	NH <sub>3</sub>	vol-ppm			≤ 25		
Hydrogen sulphide	H <sub>2</sub> S	vol-ppm			≤ 1		
Sulphur dioxide	SO <sub>2</sub>	vol-ppm			≤ 2	≤ 5	≤ 1
Nitric oxides	NO <sub>x</sub>	vol-ppm			≤ 2	≤ 2.5	≤ 2
Total sulphur	H <sub>2</sub> S+SO <sub>2</sub>	vol-ppm			≤ 1		
Oil		mg/m <sup>3</sup>				≤ 0.1	≤ 0.1
Odor			n.d.*	n.d.*		n.d.*	n.d.*

\*n.d.: not detectable

**Compliance with the current pharmacopoeia monographs**

<b>Nitrogen</b>	<ul style="list-style-type: none"> <li>• Nitrogen (Ph Eur)</li> <li>• Nitrogen, low-oxygen (Ph Eur)</li> <li>• Nitrogen (NF)</li> <li>• Nitrogen (JP)</li> </ul>
<b>Oxygen</b>	<ul style="list-style-type: none"> <li>• Oxygen (Ph Eur)</li> <li>• Oxygen (USP)</li> </ul>
<b>Carbon dioxide</b>	<ul style="list-style-type: none"> <li>• Carbon dioxide (Ph Eur)</li> <li>• Carbon dioxide (USP)</li> </ul>
<b>Synthetic air</b>	<ul style="list-style-type: none"> <li>• Air, synthetic medicinal (Ph Eur)</li> <li>• Medical air (USP)</li> </ul>
<b>Compressed air</b>	<ul style="list-style-type: none"> <li>• Air, medicinal (Ph Eur)</li> <li>• Medical air (USP)</li> </ul>
<b>Helium</b>	<ul style="list-style-type: none"> <li>• Helium (USP)</li> </ul>

