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Medicinal Gases

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MEDICINAL GASES

MEDICAL COMPRESSED AIR
Aer medicinalis

medical air; 11403

This monograph is applicable to medical compressed air, obtained by compression of atmospheric air or through the process of cryogenic liquefaction, followed by compression.

GENERAL SPECIFICATION

It contains a concentration of not less than 19.5% v/v and not more than 23.5% v/v of oxygen.

DESCRIPTION

Physical characteristics. Medical air, under normal conditions of temperature and pressure (NTP), is a colorless, tasteless, odorless, non-toxic, non-flammable gas. Medical air at 1 atm pressure and at room temperature is in a gaseous state.

Solubility. Low water solubility.

Additional Information. The analyzes of medical air described in this monograph do not need to be carried out by health service, as long as it does not produce the product locally and meets the requirements of the rules and regulations in force.

IDENTIFICATION

Complies with *Purity* requirements in *Purity Tests.*

PURITY TESTS

Purity. Proceed as described in *Determination of gas by paramagnetic analysis* **(5.8.1.3)**. The purity of the medical air must be not less than 19.5% v/v and not more than 23.5% v/v.

Water vapor. No máximo, 67 micromole/mol (ppm).

Use one of the methods described below.

A. Proceed as described in *Determination of water vapor using electrolytic hygrometer* **(5.8.2.1)**.

B. Proceed as described in *Determination of water vapor using detector tubes* **(5.8.2.2)**.

Carbon monoxide. Not more than 5 micromole/mol (ppm).

Use one of the methods described below.

A. Proceed as described in *Determination of gases by non-dispersive infrared spectroscopy* **(5.8.1.2)**.

Equipment adjustment: pass nitrogen gas of minimum purity of 99.999% v/v, containing carbon monoxide impurities < 0.5 micromole/mol (ppm), carbon dioxide < 0.5 micromole/mol (ppm), oxygen + argon < 1 micromole/mol (ppm), moisture < 2 micromole/mol (ppm), total hydrocarbons < 0.1 micromole/mol (ppm), through the sample cell for zero adjustment. Then carry out the analyzer adjustment by passing the mixture containing a concentration between 3.5 and 4.5 micromole/mol (ppm) of carbon monoxide with a minimum purity of 99.99% v/v in nitrogen of a minimum purity of 99.999 % v/v, containing carbon monoxide impurities < 0.5 micromole/mol (ppm), carbon dioxide < 0.5 micromole/mol (ppm), oxygen + argon < 1 micromole/mol (ppm), moisture < 2 micromole/mol (ppm), total hydrocarbons < 0.1 micromole/mol (ppm).

Procedure: after adjusting the equipment, pass the sample to determine the carbon monoxide content.

B. Proceed as described in *Determination of gas using detector tubes* **(5.8.1.1)**.

Carbon dioxide. Not more than 500 micromole/mol (ppm).

Use one of the methods described below.

A. Proceed as described in *Determination of gases by non-dispersive infrared spectroscopy* **(5.8.1.2)**.

Equipment adjustment: pass nitrogen gas of minimum purity of 99.999% v/v, containing carbon monoxide impurities < 0.5 micromole/mol (ppm), carbon dioxide < 0.5 micromole/mol (ppm), oxygen + argon < 1 micromole/mol (ppm), moisture < 2 micromole/mol (ppm), total hydrocarbons < 0.1 micromole/mol (ppm), through the sample cell for zero adjustment. Then carry out the analyzer adjustment by passing the mixture containing a concentration between 200 and 250 micromole/mol (ppm) of carbon monoxide with a minimum purity of 99.999% v/v in nitrogen of a minimum purity of 99.999 % v/v, containing carbon monoxide impurities < 0.5 micromole/mol (ppm), carbon dioxide < 0.5 micromole/mol (ppm), oxygen + argon < 1 micromole/mol (ppm), moisture < 2 micromole/mol (ppm), total hydrocarbons < 0.1 micromole/mol (ppm).

Procedure: after adjusting the equipment, pass the sample to determine the carbon dioxide content.

B. Proceed as described in *Determination of gas using detector tubes* **(5.8.1.1)**.

Sulfur dioxide. Not more than 1 micromole/mol (ppm).

Use one of the methods described below.

A. Proceed as described in *Determination of gases by ultraviolet spectrophotometry* **(5.8.1.4)**.

Equipment adjustment: pass nitrogen gas of minimum purity of 99.999% v/v, containing total sulfur impurities < 0.1 micromole/mol (ppm), carbon monoxide < 0.5 micromole/mol (ppm), carbon dioxide carbon < 0.5 micromole/mol (ppm), oxygen + argon < 1 micromole/mol (ppm), humidity < 2 micromole/mol (ppm), total hydrocarbons < 0.1 micromole/mol (ppm), through the sample cell for zero adjustment. Then carry out the analyzer adjustment passing the mixture containing a concentration between 0.5 and 2 micromole/mol (ppm) v/v of sulfur dioxide of minimum purity of 99.9% v/v in nitrogen, of minimum purity 99.999% v/v, containing total sulfur impurities < 0.1 micromole/mol (ppm), carbon monoxide < 0.5 micromole/mol (ppm), carbon dioxide < 0.5 micromole/mol (ppm), oxygen + argon < 1 micromole/mol (ppm), moisture < 2 micromole/mol (ppm), total hydrocarbons < 0.1 micromole/mol (ppm).

Procedure: after adjusting the equipment, pass the sample to determine the sulfur dioxide content.

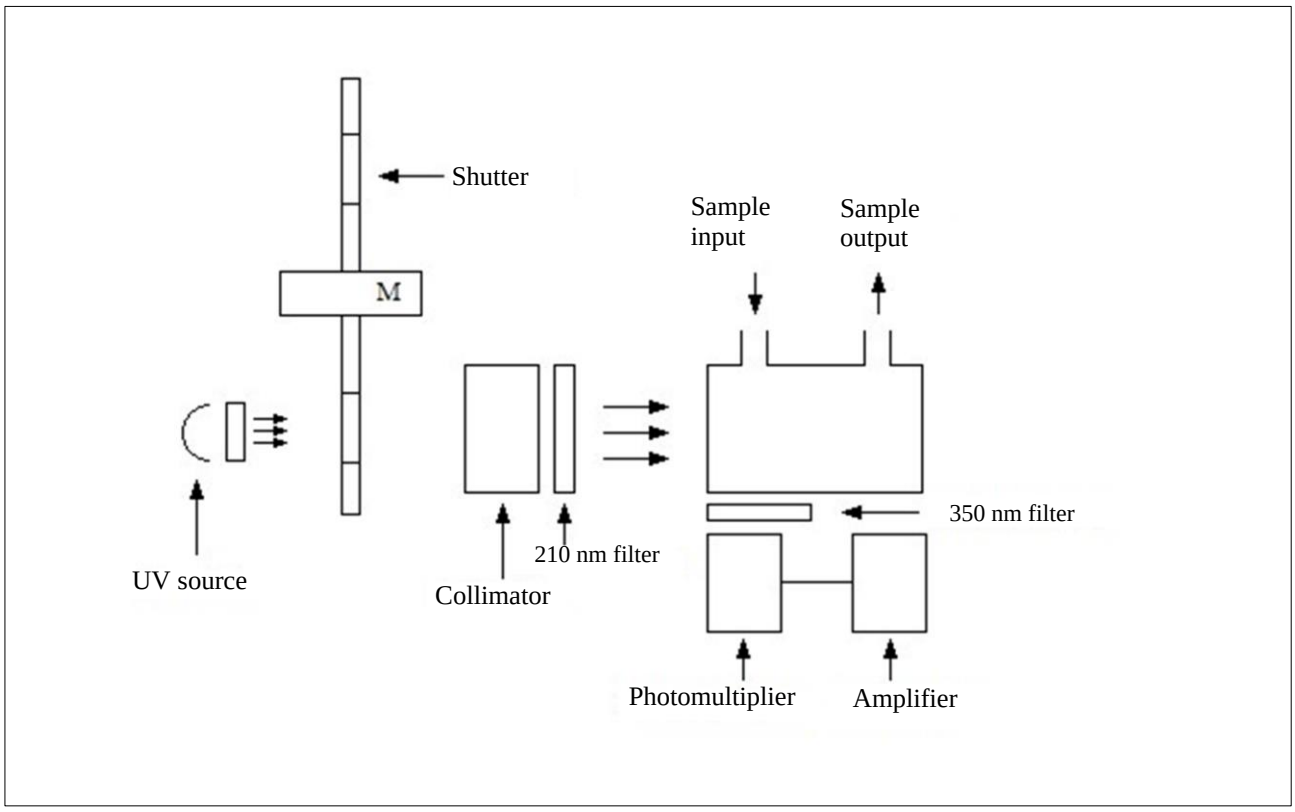

Figure 1 – UV fluorescence analyzer.

B. Proceed as described in *Determination of gas using detector tubes* **(5.8.1.1)**.

Nitrogen monoxide and nitrogen dioxide. Not more than 2 micromole/mol (ppm) total.

Use one of the methods described below.

A. Proceed as described in *Determination of gases by chemiluminescence* **(5.8.1.5)**.

Equipment adjustment: pass through the sample cell for zero adjustment the mixture containing a nominal concentration of 21% v/v of oxygen with a minimum purity of 99.999% v/v, containing nitrogen and argon impurities < 100 micromole/mol (ppm), carbon dioxide < 10 micromole/mol (ppm) and carbon monoxide < 5 micromole/mol (ppm), in 99.999% minimum purity nitrogen, containing carbon monoxide impurities < 0.5 micromole/mol (ppm), carbon dioxide < 0.5 micromole/mol (ppm), oxygen + argon < 1 micromole/mol (ppm), moisture < 2 micromole/mol (ppm), total hydrocarbons < 0.1 micromole/mol (ppm). The mixture must contain less than 0.05 micromole/mol (ppm) of nitrogen monoxide and nitrogen dioxide. Then carry out the analyzer adjustment by passing the mixture containing a nominal concentration of 2.0 micromole/mol (ppm) of nitrogen monoxide with a minimum purity of 98.0% v/v, into nitrogen of a minimum purity of 99.999% v/v, containing carbon monoxide impurities < 0.5 micromole/mol (ppm), carbon dioxide < 0.5 micromole/mol (ppm), oxygen + argon < 1 micromole/mol (ppm), moisture < 2 micromole/mol (ppm), total hydrocarbons < 0.1 micromole/mol (ppm).

Procedure: after adjusting the equipment, pass the sample to determine the content of nitrogen monoxide and nitrogen dioxide.

B. Proceed as described in *Determination of gas using detector tubes* **(5.8.1.1)**.

Oil. Not more than 0.1 micromole/mol (ppm). Proceed as described in *Determination of oil in medical gases* **(5.8.3)**, only in the case of using oil-lubricated compressors.

PACKAGING AND STORAGE

Complies with the requirements in *Medicinal gases*.

LABELLING

Comply with current legislation.

MEDICAL SYNTHETIC AIR
Aer medicinalis artificiosus

O_2; 32.00
oxygen; 11121
[*7782-44-7*]

N_2; 28.01
nitrogen; 10064
[*7727-37-9*]

This monograph is applicable to synthetic air for medical use.

GENERAL SPECIFICATION

Mixture of nitrogen and oxygen. Contains not less than 21.0% v/v and not more than 22.5% v/v oxygen.

DESCRIPTION

Physical characteristics. Colorless, odorless gas.

Solubility. At 20 ºC temperature and 101 kPa pressure, one volume of gas dissolves in approximately 50 volumes of water.

IDENTIFICATION

Complies with *Purity* requirements in *Purity Tests.*

PURITY TESTS

Purity. Proceed as described in *Determination of gases by paramagnetic analysis* **(5.8.1.3)**. The purity of the synthetic air must be not less than 21.0% v/v and not more than 22.5% v/v.

Water vapor. Not more than 67 micromole/mol (ppm).

Use one of the methods described below.

A. Proceed as described in *Determination of water vapor using electrolytic hygrometer* **(5.8.2.1)**.

B. Proceed as described in *Determination of water vapor using detector tubes* **(5.8.2.2)**.

PACKAGING AND STORAGE

Complies with the requirements in *Medicinal gases*.

LABELLING

Comply with current legislation.

CARBON DIOXIDE
Carbonei dioxidum

CO_2; 44.01
carbon dioxide; 09427
[*124-38-9*]

This monograph is applicable to carbon dioxide for medical use.

GENERAL SPECIFICATION

It contains not less than 99.0% v/v carbon dioxide in the gas phase.

DESCRIPTION

Physical characteristics. Colorless gas.

Solubility. One volume of carbon dioxide dissolves in approximately one volume of water at 20°C and a pressure of 101 kPa.

Additional Information. The gas phase must be examined. If the test is run in a cylinder, keep it at room temperature until the liquid and gas phases of the product stabilize.

IDENTIFICATION

Complies with *Purity* requirements in *Purity Tests.*

PURITY TESTS

Purity. Purity must be greater than or equal to 99.0% v/v. Proceed as described in *Determination of gas by non-dispersive infrared spectrophotometry* **(5.8.1.2)**.

Equipment adjustment: pass carbon dioxide gas of minimum purity of 99.995% v/v, containing carbon monoxide impurities < 5 micromole/mol (ppm), carbon dioxide < 25 micromole/mol (ppm), oxygen + argon < 1 micromole/mol (ppm), moisture < 2 micromole/mol (ppm), total hydrocarbons < 0.1 micromole/mol (ppm), through sample cell for zero adjustment.

Then carry out the analyzer adjustment passing the mixture with a concentration of 95% v/v of carbon dioxide with a minimum purity of 99.995% v/v, containing carbon monoxide impurities < 5 micromole/mol (ppm), oxygen < 25 micromole/mol (ppm) and nitric oxide < 1 micromole/mol (ppm), in nitrogen with a minimum purity of 99.999% v/v, containing carbon monoxide impurities < 5 micromole/mol (ppm) and oxygen < 5 micromole/mol (ppm).

Procedure: after adjusting the equipment, pass the sample to determine the carbon dioxide content.

Water vapor. No máximo, 67 micromole/mol (ppm).

Use one of the methods described below.

A. Proceed as described in *Electrolytic hygrometer* **(5.8.2.1)**.

B. Proceed as described in *Gas detector tubes* **(5.8.1.1)**.

Carbon monoxide. Not more than 5 micromole/mol (ppm).

Use one of the methods described below.

A. Proceed as described in *Gas chromatography* **(5.2.17.5)**.

Sample gas: gas to be examined.

Reference gas: mixture containing 5 micromole/mol (ppm) of carbon monoxide with a minimum purity of 99.97% v/v in nitrogen with a minimum purity of 99.999% v/v, containing carbon monoxide impurities < 0.5 micromole/mol (ppm), carbon dioxide < 0.5 micromole/mol (ppm), oxygen + argon < 1 micromole/mol (ppm), moisture < 2 micromole/mol (ppm), total hydrocarbons < 0.1 micromole/mol (ppm).

Procedure: use a chromatograph equipped with a flame ionization detector with a methanation catalyst (FID Detector); 2 m long, 4 mm inner diameter stainless-steel packed column filled with molecular sieve stationary phase; column temperature of 50 °C and detector and injector temperature of 130 °C; use helium with a minimum purity of 99.995% as carrier gas with a pressure of 25 psi and a flow of 60 mL/min.

Separately inject 0.5 mL of *Sample gas* and *Reference gas* into the gas chromatograph. Obtain the chromatograms and measure the areas under the peaks. Calculate the concentration of carbon monoxide in the *Sample gas*.

B. Proceed as described in *Gas detector tubes* **(5.8.1.1)**.

Nitrogen monoxide and nitrogen dioxide. Not more than 2 micromole/mol (ppm) total.

Use one of the methods described below.

A. Proceed as described in *Determination of medicinal gases by chemiluminescence* **(5.8.1.5)**.

Equipment adjustment: pass carbon dioxide gas of minimum purity of 99.995% v/v, containing carbon monoxide impurities < 5 micromole/mol (ppm), oxygen < 25 micromole/mol (ppm) and nitrogen monoxide < 1 micromole/mol (ppm) through sample cell for zero adjustment.

Then carry out the analyzer adjustment passing the reference mixture, containing a nominal concentration of 2.0 micromole/mol (ppm) of nitrogen monoxide of minimum purity of 98.0% v/v, in nitrogen of minimum purity 99.999 % v/v, containing carbon monoxide impurities < 0.5 micromole/mol (ppm), carbon dioxide < 0.5 micromole/mol (ppm), oxygen + argon < 1 micromole/mol (ppm), moisture < 2 micromole/mol (ppm), total hydrocarbons < 0.1 micromole/mol (ppm), or in carbon dioxide with a minimum purity of 99.995% v/v, containing carbon monoxide impurities < 5 micromole/mol (ppm) , oxygen < 25 micromole/mol (ppm) and nitrogen monoxide < 1 micromole/mol (ppm).

Procedure: after adjustment, pass the sample to determine the content of nitrogen monoxide and nitrogen dioxide.

If nitrogen is used instead of carbon dioxide in the equipment adjustment mixture, the result obtained must be multiplied by the correction factor to correct the cooling effect caused on the analyzer in response to the matrix effect of carbon dioxide.

The cooling correction factor is determined by applying a known reference mixture of nitrogen monoxide in carbon dioxide and comparing the current content with the content indicated by the analyzer that was previously calibrated with the reference mixture NO/NO_2.

$$\textit{Correction factor} = \frac{\textit{NO reading of the reference mixture in the last measurement}}{\textit{NO reading of the reference mixture in the first measurement}}$$

where

NO = nitric oxide

B. Proceed as described in *Gas detector tubes* **(5.8.1.1)**.

Total sulfur. Not more than 1 micromole/mol (ppm).

Use one of the methods described below.

A. Proceed as described in *Determination of gases by ultraviolet spectrophotometry* **(5.8.1.4)**.

The sulfur content is determined by an ultraviolet fluorescence analyzer after oxidation of the sulfur compounds by heating to a temperature of 1000 °C.

Equipment adjustment: pass carbon dioxide gas of minimum purity of 99.995% v/v, containing carbon monoxide impurities < 5 micromole/mol (ppm), oxygen < 25 micromole/mol (ppm) and nitrogen monoxide < 1 micromole/mol (ppm) through sample cell for zero adjustment.

Then carry out the analyzer adjustment passing the reference mixture containing a concentration between 0.5 and 2 micromole/mol (ppm) v/v of hydrogen sulfide with a minimum purity of 99.7% v/v in hydrogen dioxide carbon with a minimum purity of 99.995% v/v, containing carbon monoxide impurities < 5 micromole/mol (ppm), oxygen < 25 micromole/mol (ppm) and nitrogen monoxide < 1 micromole/mol (ppm).

Procedure: after adjusting the equipment, pass the sample through a quartz oven previously heated to 1000 ºC. Oxygen gas, with a minimum purity of 99.99% v/v, containing carbon monoxide impurities < 5 micromole/mol (ppm), carbon dioxide < 10 micromole/mol (ppm) and nitrogen and argon < 100 micromole/mol (ppm), circulates in the oven up to 1/10 of the sample flow rate. Determine the sulfur dioxide content in the gas mixture released from the oven.

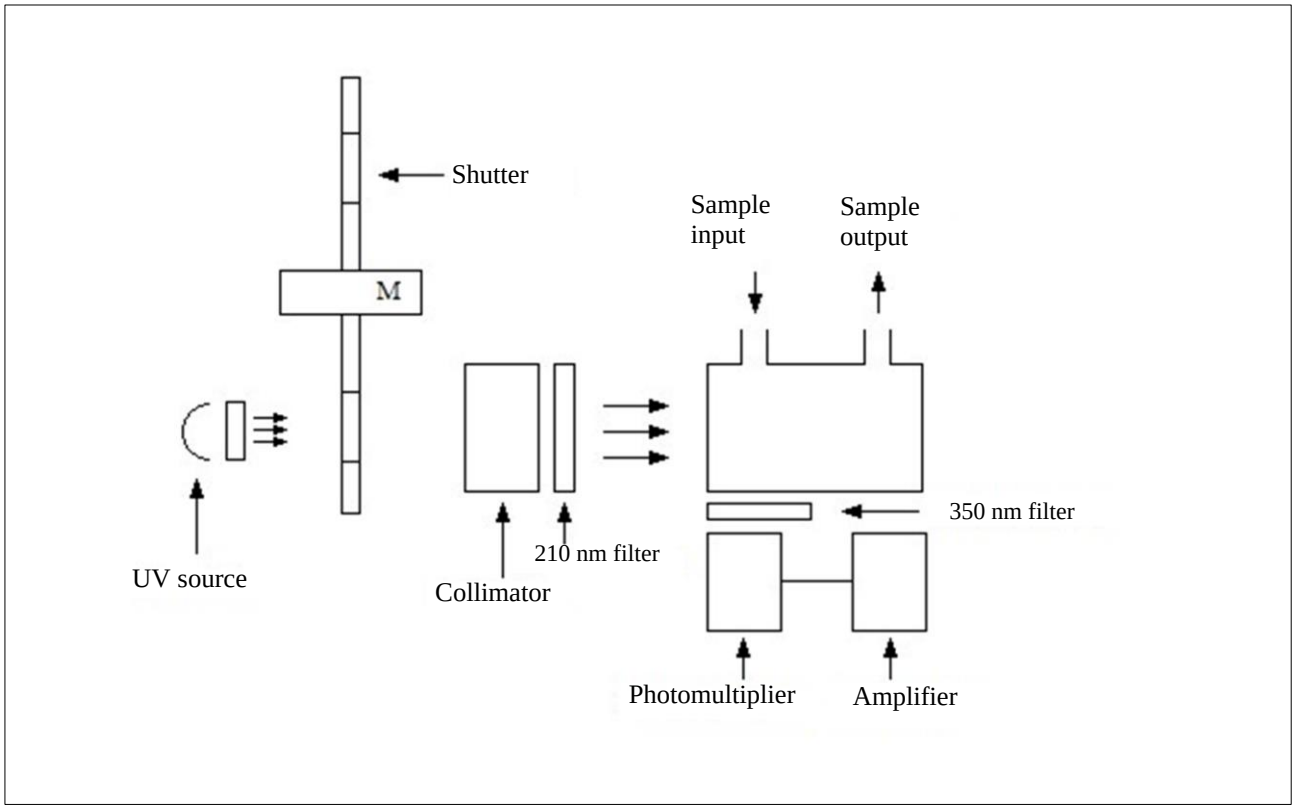

Figure 1 – UV fluorescence analyzer.

B. Proceed as described in *Gas detector tubes* **(5.8.1.1)**.

PACKAGING AND STORAGE

Complies with the requirements in *Medicinal gases*.

LABELLING

Comply with current legislation.

OXYGEN
Oxygenium

O = O

O_2; 32.00
oxygen; 11121
[*7782-44-7*]

This monograph is applicable to oxygen for medical use, compressed or not, obtained through the process of cryogenic liquefaction.

GENERAL SPECIFICATION

Contains oxygen at purity not less than 99.0% v/v.

DESCRIPTION

Physical characteristics. Oxygen, under normal conditions of temperature and pressure (NTP), is a colorless, tasteless, odorless, non-toxic, oxidizer, non-combustible gas. Oxygen at 1 atm pressure and at -183 ºC temperature is in a liquid (cryogenic) state and has a slightly bluish color.

Solubility. Low water solubility. One volume of oxygen dissolves in approximately 32 volumes of water and seven volumes of ethyl alcohol (95 °GL) at 20 °C and a pressure of 101.3 kPa.

Physicochemical constants. 1000 mL of oxygen at 0 °C and a pressure of 101.3 kPa weighs around 1.429 g.

IDENTIFICATION

Complies with *Purity* requirements in *Purity Tests.*

PURITY TESTS

Purity. Proceed as described in *Determination of gases by paramagnetic analysis* **(5.8.1.3)**. Purity must be greater than or equal to 99.0% v/v.

Water vapor. No máximo, 67 micromole/mol (ppm).

Use one of the methods described below.

A. Proceed as described in *Determination of water vapor using electrolytic hygrometer* **(5.8.2.1)**.

B. Proceed as described in *Determination of water vapor using detector tubes* **(5.8.2.2)**.

Note: *The following tests (Carbon Monoxide and Carbon Dioxide) should only be carried out for products that are filled in cylinders. Therefore, liquid products stored in cryogenic tanks and tank trucks are exempt from carrying out the following tests.*

Carbon monoxide. Not more than 5 micromole/mol (ppm).

Use one of the methods described below.

A. Proceed as described in *Determination of gases by non-dispersive infrared spectroscopy* **(5.8.1.2)**.

Equipment adjustment: pass nitrogen gas of minimum purity of 99.999% v/v, containing carbon monoxide impurities < 0.5 micromole/mol (ppm), carbon dioxide < 0.5 micromole/mol (ppm), oxygen + argon < 1 micromole/mol (ppm), moisture < 2 micromole/mol (ppm), total hydrocarbons < 0.1 micromole/mol (ppm), through the sample cell for zero adjustment. Then carry out the analyzer adjustment by passing the mixture containing a concentration between 3.5 and 4.5 micromole/mol (ppm) of carbon monoxide with a minimum purity of 99.99% v/v in nitrogen of a minimum purity of 99.999 % v/v, containing carbon monoxide impurities < 0.5 micromole/mol (ppm), carbon dioxide < 0.5 micromole/mol (ppm), oxygen + argon < 1 micromole/mol (ppm), moisture < 2 micromole/mol (ppm), total hydrocarbons < 0.1 micromole/mol (ppm).

Procedure: after adjusting the equipment, pass the sample to determine the carbon monoxide content.

B. Proceed as described in *Determination of gas using detector tubes* **(5.8.1.1)**.

Carbon dioxide. Not more than 300 micromole/mol (ppm).

Use one of the methods described below.

A. Proceed as described in *Determination of gases by non-dispersive infrared spectroscopy* **(5.8.1.2)**.

Equipment adjustment: pass nitrogen gas of minimum purity of 99.999% v/v, containing carbon monoxide impurities < 0.5 micromole/mol (ppm), carbon dioxide < 0.5 micromole/mol (ppm), oxygen + argon < 1 micromole/mol (ppm), moisture < 2 micromole/mol (ppm), total hydrocarbons < 0.1 micromole/mol (ppm), through the sample cell for zero adjustment. Then carry out the analyzer adjustment by passing the mixture containing a concentration between 200 and 250 micromole/mol (ppm) of carbon monoxide with a minimum purity of 99.999% v/v in nitrogen of a minimum purity of 99.999 % v/v, containing carbon monoxide impurities < 0.5 micromole/mol (ppm), carbon dioxide < 0.5 micromole/mol (ppm), oxygen + argon < 1 micromole/mol (ppm), moisture < 2 micromole/mol (ppm), total hydrocarbons < 0.1 micromole/mol (ppm).

Procedure: after adjusting the equipment, pass the sample to determine the carbon dioxide content.

B. Proceed as described in *Determination of gas using detector tubes* **(5.8.1.1)**.

PACKAGING AND STORAGE

Complies with the requirements in *Medicinal gases*.

LABELLING

Comply with current legislation.