KENYA STANDARD **DKS 2170-4:2009**

Medical Gases —Specification

Part 4:

Medical Carbon Dioxide

PUBLIC REVIEW DRAFT MAY 2009

 First Edition 2009

TECHNICAL COMMITTEE REPRESENTATION

The following organizations were represented on the Technical Committee:

Consumer Information Network
BOC Kenya Ltd
Noble Gases International Ltd
Chemigas Ltd
Synergy Gases (K) Ltd
Carbacid (CO_2) Ltd
Government Chemist's Department
Kenya Industrial Research and Development Institute (KIRDI)
Kenyatta University, Chemistry Dept
Kenya Science Teachers College
Ministry of Roads and Public Works – Materials Branch
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REVISION OF KENYA STANDARDS

In order to keep abreast of progress in industry, Kenya Standards shall be regularly reviewed. Suggestions for improvements to published standards, addressed to the Managing Director, Kenya Bureau of Standards, are welcome.

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Part 4:

Medical Carbon Dioxide

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Foreword

This standard has been prepared by the Technical Committee on Gases under the guidance of the Standards Projects Committee, and it is in accordance with the procedures of the Kenya Bureau of Standards.

Medical Carbon Dioxide covered in this standard is intended for use in the medical sector and this standard cover characteristics touching on their safety, packaging and marking.

The standard specifies limits on impurities such as carbon monoxide, Hydrogen Sulphide, Sulphur Dioxide, Nitrogen Monoxide, Nitrogen dioxide and water.

Identity and purity requirements are also covered in this standard.

During the development of this standard, reference was made to the following documents:

British Pharmacopoeia online 2008— Carbon Dioxide Monograph

British Pharmacopoeia online 2008—Gas detector tubes (Ph. Eur. text 2.1.6)

Acknowledgement is hereby made for the assistance received from these sources.

Medical Gases —Specification

Part 4:

Medical Carbon Dioxide

1 Scope

This standard prescribes the requirements and test methods for compressed Carbon dioxide for medical use.

2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this Kenya Standard. For undated reference, the latest edition of the normative document referred to applies.

KS ISO 32*, Gas cylinders for medical use — Marking for identification of content*

KS ISO 7225*, Gas cylinders — Precautionary labels*

KS 09-532, *Specification for standard atmospheric conditions for test purposes*

3 Terms and Definitions

For the purposes of this Standard the following terms and definitions shall apply.

3.1
R
reagent

STP
standard atmospheric temperature and pressure as per KS 09-532

4 Requirements

4.1 Purity

When tested in accordance with the method specified in annex A, the product shall have a minimum of 99.5 % v/v Carbon dioxide content.

4.2 Identity

When tested in accordance with the method specified in annex B, the product shall pass the test.

4.3 Impurities

The product shall be colourless gas and shall comply with the impurities limits given table 1.

Table 1 - Impurity limits for Medical Carbon Dioxide

SL NO.	Characteristic	Requirement	Test method
1.	Carbon monoxide ppm v/v, max	5	Annex C
2.	Hydrogen Sulphide ppm v/v, max	1	Annex D
3.	Sulphur Dioxide ppm v/v, max	2	Annex E
4.	Nitrogen Monoxide and nitrogen dioxide ppm v/v, max	2	Annex F
5.	Water ppm v/v , max	60	Annex G

5 Packing and marking

5.1 Packing

The product shall be supplied as compressed gas in appropriate steel cylinders complying with relevant Kenya standards. Valves or taps shall not be lubricated with oil or grease.

5.2 Marking

5.2.1 Cylinder

Each cylinder shall be clearly and indelibly marked with the following information:

a) The words “Medical Carbon Dioxide”;

b) The name or registered trade mark and address of the manufacturer;

c) Purity;

d) The impurities limits in table 1, as applicable;

e) Batch number and;

f) Date of filling;

g) Filling pressure (at STP).

5.2.2 Colour and chemical formula

Each cylinder shall in addition to the markings in 5.2.1, be clearly and indelibly marked with the colour and chemical formula corresponding to Carbon Dioxide as specified in KS ISO 32.

5.2.3 Precautionary labels

Each cylinder shall in addition to the markings in 5.2.1, be clearly and indelibly marked with precautionary labels as specified in KS ISO 7225.

Annex A

(Normative)

Determination of Carbon Dioxide content

A.1 Principle

This method covers the determination of Carbon Dioxide content by Infrared analyser. Examine the gaseous phase. If the test is performed on a cylinder of gas, keep the cylinder of the substance to be examined at room temperature for not less than 6 h before carrying out the tests. Keep the cylinder in the vertical position with the outlet valve uppermost.

A.2 Apparatus

Infrared analyser

Spectrophotometers for recording spectra consist of a suitable light source, monochromator or interferometer and detector.

Fourier transform spectrophotometers use polychromatic radiation and calculate the spectrum in the frequency domain from the original data by Fourier transformation.

Spectrophotometers fitted with an optical system capable of producing monochromatic radiation in the measurement region may also be used.

Normally the spectrum is given as a function of transmittance, the quotient of the intensity of the transmitted radiation and the incident radiation. It may also be given in absorbance.

The absorbance (*A*) is defined as the logarithm to base 10 of the reciprocal of the transmittance (*T*):

$$A = \log_{10}\left(\frac{1}{T}\right) = \log_{10}\left(\frac{I_0}{I}\right)$$

$$T = \frac{I}{I_0},$$

I_0= intensity of incident radiation,

I= intensity of transmitted radiation.

A.3 Reagents

A.3.1 Reference gas (a) carbon dioxide R1.

Carbon dioxide containing not less than 99.995% v/v of CO_2;

Carbon monoxide Less than 5 ppm;

Oxygen Less than 25 ppm.

A.3.2 Nitrogen R1

Nitrogen containing not less than 99.999% v/v of N_2;

Carbon monoxide Less than 1 ppm;

Oxygen Less than 5 ppm;

A.3.3 Reference gas (b) A mixture containing 95.0 per cent V/V of Carbon dioxide R1 and 5.0 per cent V/V of Nitrogen R1

A.3.4 Nitrogen, R

Nitrogen N_2 = 28.01 (7727-37-9)

Laboratory cylinder grade of commerce, washed with water and dried.

B.3.5 Argon, R

Argon Ar = 39.95 (7440-37-1)

Laboratory cylinder grade of commerce containing not less than 99.995% v/v of Ar.

A.4 Procedure

A.4.1 Use a cell transparent to infrared radiation and of suitable optical path length (for example, 1-20 m).

A.4.2 Evacuate the cell and fill to the desired pressure through a stopcock or needle valve using a suitable gas transfer line between the cell and the container of the gas to be examined.

A.4.3 Calibrate the apparatus and set the sensitivity using reference gases (a) and (b).

A.4.4 Filter the substance to be examined to avoid stray light phenomena.

A.4.5 If necessary adjust the pressure in the cell to atmospheric pressure using a gas transparent to infrared radiation (for example nitrogen R and argon R).

A.4.6 To avoid absorption interferences due to water, carbon dioxide or other atmospheric gases, place in the reference beam, if possible, an identical cell that is either evacuated or filled with the gas transparent to infrared radiation.

A.4.7 Measure the content of carbon dioxide in the gas to be examined.

Annex B

(Normative)

Identity test method

Identify of carbon dioxide is established by conducting Infrared absorption spectrophotometry (IR) and Glowing splinter and Barium hydroxide solution tests

B.1 Infrared absorption spectrophotometry (IR) test

B.1.1 Principle

This method covers the determination of identity of Carbon dioxide by means of an Infrared absorption spectrophotometry (IR) test. The infrared absorption spectrum is concordant with the reference spectrum of Carbon dioxide.

B.1.2 Apparatus

Infrared analyzer

B.1.3 Procedure

B.1.3.1 Compare IR spectrum of the test sample obtained in A.4.7 and that of the reference gas R1 in A.3.

B.1.3.2 The test gas shall be deemed to have passed this test if its infrared absorption spectrum is concordant with the reference spectrum of Carbon dioxide.

B.2 Glowing splinter and Barium hydroxide solution tests.

B.2.1 Principle

This method covers the determination of identity of Carbon Dioxide by means of glowing splinter and Barium hydroxide solution tests.

B.2.2 Reagents

B.2.2.1 Barium hydroxide solution R

4.73% w/v solution of Barium Hydroxide

B.2.2.2 Dilute Acetic Acid, R

Dilute 12 g glacial acetic acid to 100 ml with water. It contains not less than 11.5% and not more than 12.5% w/v of $C_2H_4O_2$ (2m).

B.2.3 Materials

A splinter of wood

B.2.4 Procedure

B.2.4.1 Place a glowing splinter of wood in an atmosphere of the substance to be examined. It is extinguished.

B.2.4.2 Pass a stream of the substance to be examined through *barium hydroxide solution R*. A white precipitate is formed which dissolves with effervescence in *dilute acetic acid R*.

B.2.4.3 The test gas shall be deemed to have passed identity test if the splinter is extinguished as per B.2.4.1 and the white precipitate is formed which dissolves with effervescence in *dilute acetic acid R* as per B.2.4.2.

Annex C

(Normative)

Determination of Carbon Monoxide content

C.1 Principle

This method covers the determination of carbon monoxide content of carbon dioxide using a carbon monoxide detector tube.

Gas detector tubes are cylindrical, sealed tubes consisting of an inert transparent material and are constructed to allow the passage of gas. They contain reagents adsorbed onto inert substrates that are suitable for the visualization of the substance to be detected and, if necessary, they also contain preliminary layers and/or adsorbent filters to eliminate substances that interfere with the substance to be detected.

The layer of indicator contains either a single reagent for the detection of a given impurity or several reagents for the detection of several substances (monolayer tube or multilayer tube).

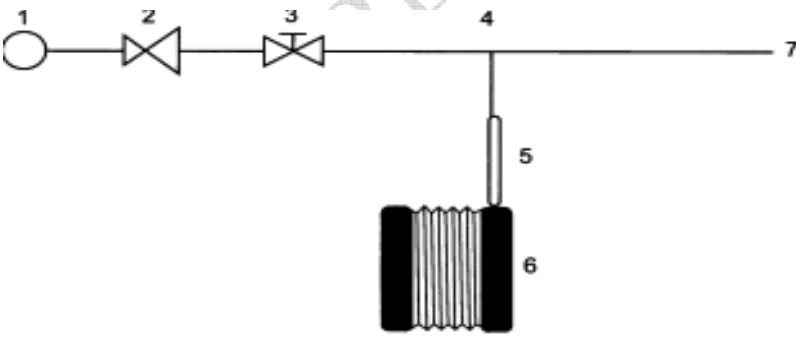
The test is carried out by passing the required volume of the gas to be examined through the indicator tube. The length of the coloured layer or the intensity of a colour change on a graduated scale gives an indication of the impurities present. The calibration of the detector tubes is verified according to the manufacturer's instructions.

Note 1 If the analysis is performed on a cylinder, keep the cylinder of the gas to be examined at room temperature for at least 6 h before carrying out the tests. Keep the cylinder in the vertical position with the outlet valve uppermost.

C.3.2 Apparatus

C.3.2.1 Carbon Monoxide Detector tube

A cylindrical, sealed glass tube containing adsorbent filters and suitable supports for di-iodine pentoxide, selenium dioxide and fuming sulphuric acid indicators(Figure 1). The minimum value indicated is 5 ppm or less, with a relative standard deviation of at most ± 15 %. Tubes can be verified with a calibration gas containing the appropriate impurity, if a negative result is obtained.



1. Gas supply
2. Pressure regulator
3. Needle valve
4. "Y"-piece
5. Indicator tube
6. Indicator tube pump
7. End open to atmosphere

Figure 1- Apparatus for gas detector tube

C.3. 3 Reagents

Calibration gas mixtures

C.3. 4 Procedure

C.3. 4.1 Verify the calibration of the detector tube according to the manufacturer's instructions.

C.3. 4.2 The gas supply is connected to a suitable pressure regulator and needle valve. Connect the flexible tubing fitted with a Y-piece to the valve and adjust the flow of gas to be examined to purge the tubing in order to obtain an appropriate flow (Figure 1).

C.3. 4.3 Prepare the indicator tube and fit to the metering pump, following the manufacturer's instructions.

C.3. 4.4 Connect the open end of the indicator tube to the short leg of the tubing and operate the pump by the appropriate number of strokes to pass a suitable volume of gas to be examined through the tube.

C.3. 4.5 Read the value corresponding to the length of the coloured layer or the intensity of the colour on the graduated scale and report this as the carbon monoxide content. If a negative result is achieved, indicator tubes can be verified with a calibration gas containing the appropriate impurity.

Annex D

(Normative)

Determination of Hydrogen sulphide content

D.1 Principle

This method covers the determination of hydrogen sulphide content of Carbon dioxide using a Hydrogen sulphide detector tube**.**

Gas detector tubes are cylindrical, sealed tubes consisting of an inert transparent material and are constructed to allow the passage of gas. They contain reagents adsorbed onto inert substrates that are suitable for the visualization of the substance to be detected and, if necessary, they also contain preliminary layers and/or adsorbent filters to eliminate substances that interfere with the substance to be detected.

The layer of indicator contains either a single reagent for the detection of a given impurity or several reagents for the detection of several substances (monolayer tube or multilayer tube).

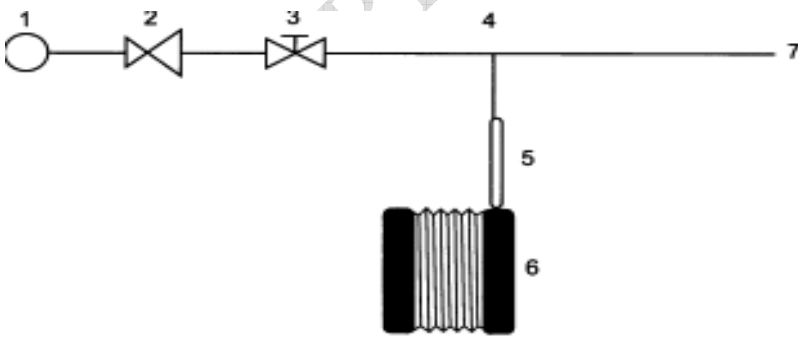
The test is carried out by passing the required volume of the gas to be examined through the indicator tube. The length of the coloured layer or the intensity of a colour change on a graduated scale gives an indication of the impurities present. The calibration of the detector tubes is verified according to the manufacturer's instructions

Note 1 If the analysis is performed on a cylinder, keep the cylinder of the gas to be examined at room temperature for at least 6 h before carrying out the tests. Keep the cylinder in the vertical position with the outlet valve uppermost.

D.3.2 Apparatus

D.3.2.1 Hydrogen sulphide detector tube

Sealed glass tube containing adsorbent filters and suitable supports for an appropriate lead salt indicator(Figure 2). The minimum value indicated is 1 ppm or less, with a relative standard deviation of at most ± 10 per cent. Tubes can be verified with a calibration gas containing the appropriate impurity, if a negative result is obtained.



1. Gas supply
2. Pressure regulator
3. Needle valve
4. "Y"-piece
5. Indicator tube
6. Indicator tube pump
7. End open to atmosphere

Figure 2- Apparatus for gas detector tube

D.3.3 Reagents

D.3.3.1 calibration gas mixtures

D.3.4 Procedure

D.3. 4.1 Verify the calibration of the detector tube according to the manufacturer's instructions.

D.3. 4.2 The gas supply is connected to a suitable pressure regulator and needle valve. Connect the flexible tubing fitted with a Y-piece to the valve and adjust the flow of gas to be examined to purge the tubing in order to obtain an appropriate flow (Figure 2).

D.3. 4.3 Prepare the indicator tube and fit to the metering pump, following the manufacturer's instructions.

D.3. 4.4 Connect the open end of the indicator tube to the short leg of the tubing and operate the pump by the appropriate number of strokes to pass a suitable volume of gas to be examined through the tube.

D.3. 4.5 Read the value corresponding to the length of the coloured layer or the intensity of the colour on the graduated scale and report this as the hydrogen sulphide content. If a negative result is achieved, indicator tubes can be verified with a calibration gas containing the appropriate impurity**.**

Annex E
(Normative)

Determination of sulphur dioxide content

E.1 Principle

This method covers the determination of sulphur dioxide content of Carbon Dioxide using a sulphur dioxide detector tube.

Gas detector tubes are cylindrical, sealed tubes consisting of an inert transparent material and are constructed to allow the passage of gas. They contain reagents adsorbed onto inert substrates that are suitable for the visualization of the substance to be detected and, if necessary, they also contain preliminary layers and/or adsorbent filters to eliminate substances that interfere with the substance to be detected.

The layer of indicator contains either a single reagent for the detection of a given impurity or several reagents for the detection of several substances (monolayer tube or multilayer tube).

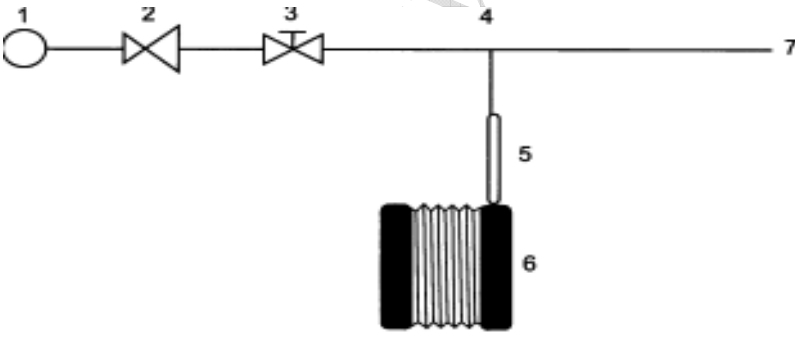
The test is carried out by passing the required volume of the gas to be examined through the indicator tube. The length of the coloured layer or the intensity of a colour change on a graduated scale gives an indication of the impurities present. The calibration of the detector tubes is verified according to the manufacturer's instructions.

Note 1 If the analysis is performed on a cylinder, keep the cylinder of the gas to be examined at room temperature for at least 6 h before carrying out the tests. Keep the cylinder in the vertical position with the outlet valve uppermost.

E.2 Apparatus

E.2.1 Sulphur dioxide detector tube

Sealed glass tube containing adsorbent filters and suitable supports for the iodine and starch indicator (Figure 3). The minimum value indicated is 0.5 ppm with a relative standard deviation of at most ± 15 %. Tubes can be verified with a calibration gas containing the appropriate impurity, if a negative result is obtained.



1. Gas supply
2. Pressure regulator
3. Needle valve
4. "Y"-piece
5. Indicator tube
6. Indicator tube pump
7. End open to atmosphere

Figure 3 — Apparatus for gas detector tube

E.3 Reagents

E.3.1 calibration gas mixtures

E.4 Procedure

E.4.1 Verify the calibration of the detector tube according to the manufacturer's instructions.

E.4.2 The gas supply is connected to a suitable pressure regulator and needle valve. Connect the flexible tubing fitted with a Y-piece to the valve and adjust the flow of gas to be examined to purge the tubing in order to obtain an appropriate flow (Figure 3).

E.4.3 Prepare the indicator tube and fit to the metering pump, following the manufacturer's instructions.

E.4.4 Connect the open end of the indicator tube to the short leg of the tubing and operate the pump by the appropriate number of strokes to pass a suitable volume of gas to be examined through the tube.

E.4.5 Read the value corresponding to the length of the coloured layer or the intensity of the colour on the graduated scale and report this as the sulphur dioxide content. If a negative result is achieved, indicator tubes can be verified with a calibration gas containing the appropriate impurity.

Annex F
(Normative)

Determination of nitrogen monoxide and nitrogen dioxide

F.1 Principle

This method covers the determination of nitrogen monoxide and nitrogen dioxide content of nitrous oxide using a nitrogen monoxide and nitrogen dioxide detector tube.

Note 1 If the analysis is performed on a cylinder, keep the cylinder of the gas to be examined at room temperature for at least 6 h before carrying out the tests. Keep the cylinder in the vertical position with the outlet valve uppermost.

F.2 Apparatus

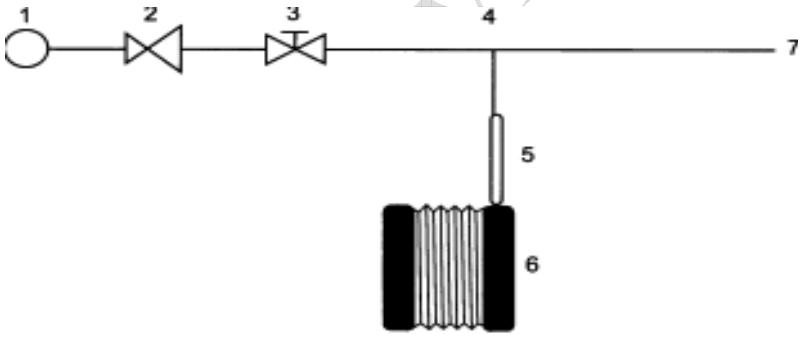
F.2.1 Nitrogen monoxide and nitrogen dioxide detector tube

A cylindrical, sealed glass tube containing adsorbent filters and suitable supports for an oxidizing layer Cr (VI) salt and the diphenyl-benzidine indicator (Figure 4).The minimum value indicated is 0.5 ppm or less, with a relative standard deviation of at most ± 15 %Tubes can be verified with a calibration gas containing the appropriate impurity, if a negative result is obtained.

Gas detector tubes are cylindrical, sealed tubes consisting of an inert transparent material and are constructed to allow the passage of gas. They contain reagents adsorbed onto inert substrates that are suitable for the visualization of the substance to be detected and, if necessary, they also contain preliminary layers and/or adsorbent filters to eliminate substances that interfere with the substance to be detected.

The layer of indicator contains either a single reagent for the detection of a given impurity or several reagents for the detection of several substances (monolayer tube or multilayer tube).

The test is carried out by passing the required volume of the gas to be examined through the indicator tube. The length of the coloured layer or the intensity of a colour change on a graduated scale gives an indication of the impurities present. The calibration of the detector tubes is verified according to the manufacturer's instructions.



1. Gas supply
2. Pressure regulator
3. Needle valve
4. "Y"-piece
5. Indicator tube
6. Indicator tube pump
7. End open to atmosphere

Figure 4 — Apparatus for gas detector tube

F.3 Reagents

F.3.1 calibration gas mixtures

F.4 Procedure

F.4.1 Verify the calibration of the detector tube according to the manufacturer's instructions.

F.4.2 The gas supply is connected to a suitable pressure regulator and needle valve. Connect the flexible tubing fitted with a Y-piece to the valve and adjust the flow of gas to be examined to purge the tubing in order to obtain an appropriate flow (Figure 4).

F.4.3 Prepare the indicator tube and fit to the metering pump, following the manufacturer's instructions.

F.4.4 Connect the open end of the indicator tube to the short leg of the tubing and operate the pump by the appropriate number of strokes to pass a suitable volume of gas to be examined through the tube.

F.4.5 Read the value corresponding to the length of the coloured layer or the intensity of the colour on the graduated scale and report this as the nitrogen monoxide and nitrogen dioxide content. If a negative result is achieved, indicator tubes can be verified with a calibration gas containing the appropriate impurity.

Annex G

(Normative)

Determination of water content

G.1 Principle

This method covers the determination of water content of Oxygen using a water vapour detector tube.

Gas detector tubes are cylindrical, sealed tubes consisting of an inert transparent material and are constructed to allow the passage of gas. They contain reagents adsorbed onto inert substrates that are suitable for the visualization of the substance to be detected and, if necessary, they also contain preliminary layers and/or adsorbent filters to eliminate substances that interfere with the substance to be detected.

The layer of indicator contains either a single reagent for the detection of a given impurity or several reagents for the detection of several substances (monolayer tube or multilayer tube).

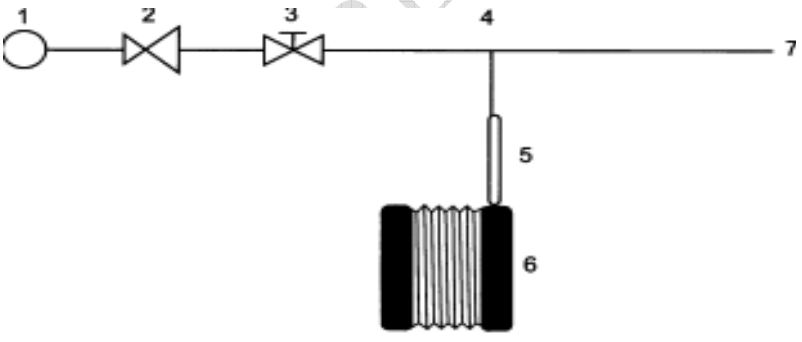
The test is carried out by passing the required volume of the gas to be examined through the indicator tube. The length of the coloured layer or the intensity of a colour change on a graduated scale gives an indication of the impurities present. The calibration of the detector tubes is verified according to the manufacturer's instructions.

Note 1 If the analysis is performed on a cylinder, keep the cylinder of the gas to be examined at room temperature for at least 6 h before carrying out the tests. Keep the cylinder in the vertical position with the outlet valve uppermost.

G.2 Apparatus

G.2.1 Water vapour detector tube

Sealed glass tube containing adsorbent filters and suitable supports for the magnesium perchlorate indicator(Figure 5).The minimum value indicated is 60 ppm or less, with a relative standard deviation of at most ± 20 per centTubes can be verified with a calibration gas containing the appropriate impurity, if a negative result is obtained.



1. Gas supply
2. Pressure regulator
3. Needle valve
4. "Y"-piece
5. Indicator tube
6. Indicator tube pump
7. End open to atmosphere

Figure 5- Apparatus for gas detector tube

G.3 Reagents

G.3.1 calibration gas mixtures

G.4 Procedure

G.3. 4.1 Verify the calibration of the detector tube according to the manufacturer's instructions.

G.3. 4.2 The gas supply is connected to a suitable pressure regulator and needle valve. Connect the flexible tubing fitted with a Y-piece to the valve and adjust the flow of gas to be examined to purge the tubing in order to obtain an appropriate flow (Figure 5).

G.3. 4.3 Prepare the indicator tube and fit to the metering pump, following the manufacturer's instructions.

G.3. 4.4 Connect the open end of the indicator tube to the short leg of the tubing and operate the pump by the appropriate number of strokes to pass a suitable volume of gas to be examined through the tube.

G.3. 4.5 Read the value corresponding to the length of the coloured layer or the intensity of the colour on the graduated scale and report this as the water content. If a negative result is achieved, indicator tubes can be verified with a calibration gas containing the appropriate impurity.

