

FINALIZED TANZANIA STANDARD

Gaseous Oxygen for medical use – Specification

TANZANIA BUREAU OF STANDARDS

2nd edition

0. FOREWORD

0.1. This Tanzania Draft Standard was prepared by the Technical Committee, CDC 09 – Gases Products under the supervision of Chemicals Standards Divisional Committee, and it is in accordance with the procedures of the bureau.

0.2. In the preparation of this standard assistance was derived from:

SANAS 532:2009 - Standard and specifications for industrial, medical, propellant, food and beverage gases, refrigerants and breathing gases, published by the South African National Standards.

European Pharmacopoeia – Specification, 2007, published by European Directorate for the Quality of Medicines - Council of Europe (COE)

British Pharmacopoeia - Specification, 2007 published by British Pharmacopoeia Commission

0.3. For the purpose of deciding whether a particular requirement of this standard is complied with, the final value observed or calculated expressing the result(s) of a test or analysis shall, be rounded off in accordance with TZS 4:1979 (see clause 2). The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

1. SCOPE

1.1. This Draft Tanzania standard specifies requirements, methods of sampling and test for oxygen gas that is intended to be used for medical applications.

1.2. This draft Tanzania Standard does not apply to oxygen for industrial, breathing, electronic or other applications.

2. Normative references

The following normative references are indispensable for the application of this standard. For dated references, only the edition cited applies. For undated references, the latest edition of the normative references (including amendments) applies

TZS 4, *Rounding off numerical values*

TZS 59, *Water – distilled quality – Specification*

TZS 97, *Specification for identification of contents of industrial gas cylinders*

3. Requirements

3.1. General requirements

3.1.1. Gaseous oxygen for medical use shall be colourless and odourless.

3.1.2. Gaseous oxygen for medical use bursts into flame when in contact with the glowing splinter.

3.2. Specific requirements

The gaseous oxygen for medical use shall comply with specific requirements specified in Table 1 when tested in accordance with the methods prescribed therein.

Table 1 Specific requirements of oxygen for medical use

S/ No.	Characteristic	Requirement	Test method
(i)	Oxygen, %, (v/v), min.	99.5	Annex A
(ii)	Water vapour, ppm, max.	67	Annex B
(iii)	Carbon monoxide, µl/l, max.	5	Annex C
(iv)	Carbon dioxide, µl/l, max.	300	Annex D
(v)	Methane, v/v, max.	50×10^{-6}	Annex E

NOTE:
 Oxygen gas produced by air separation process shall not normally contain any carbon dioxide, carbon monoxide and hydrocarbon in terms of methane. Presence of these impurities in gaseous oxygen of technical grade normally is expected from other methods of production.

4. Sampling

Sampling and criteria of finding conformity of the requirements of this standard shall be done in accordance with method described in Annex F.

5. Packaging, marking and Transportation

5.1. Packaging

5.1.1. The gaseous oxygen for medical use shall be supplied in compressed gas cylinder (s).

5.2. The conditions of cylinders shall be such as not to be detrimental to the purity of the medical Oxygen during normal transportation and storage. **Marking**

The marking and labelling shall be in accordance with TZS 97.

5.3 Transportation

5.3.1 The conditions of road tank vehicles shall be such as not to be detrimental to the purity of the medical Oxygen during normal transportation and storage

5.3.2 Where applicable, transport by road shall comply with the requirements of respective cylinders, in case of cylinders, road tank vehicles and any other information relevant to maintain the quality of the product.

6. Quality of reagents

Analytical grade reagents and distilled water that comply with TZS 59 or deionized water of equivalent purity shall be used for the appropriate tests.

Annex A (Normative)

Determination of oxygen content

A.1 Principle

The method uses the principle of paramagnetic susceptibility, a physical property which is considerably greater in oxygen than in other common gases. Oxygen Molecules are more strongly attracted by a magnetic field than are molecules of other gases, most of which are slightly diamagnetic (repelled by a magnetic field). Magneto-dynamic oxygen analyzer are based on Faraday's method of determining the magnetic susceptibility of a gas by measuring the force developed by a strong non-uniform magnetic field on a diamagnetic test body suspended in the sample gas. The test body of all measuring of two nitrogen-field quartz spheres arranged in the form of a dumb-bell, as shown in figure A.1. A single turn of fine platinum wire (the feedback coil) is secured in place around the dumb-bell. A rugged, taut band platinum ribbon suspension attached to the mid-point of the dumb-bell positions the dumb-bell in the strong non-uniform magnetic field existing between the specially pole pieces of the permanent magnetic structure (see figure A.2).

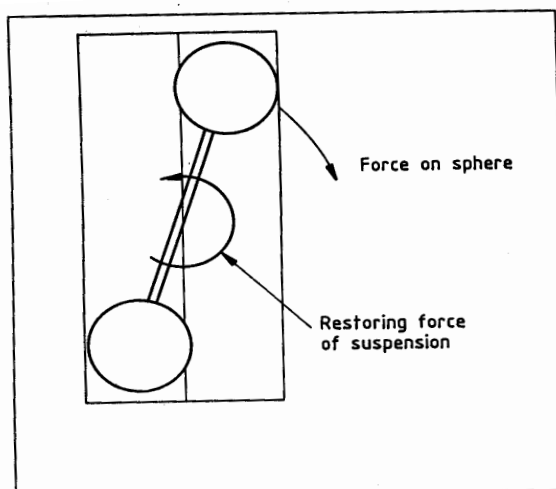


Figure A.1 Dumb bell system: forces within the cell

A.2 Apparatus

A variety of analytical equipment suppliers provide simple, ready to run portable units for this purpose, which may be powered either by battery or mains electricity. Figure A.3 illustrates the configuration of a typical unit designed for this purpose.

A.3 Calibration

Calibration of these units shall be carried out using a calibration standard that is assured by analysis traceability gravimetrically to national standards and of purity 99.95% oxygen and manufacturer's instructions.

A.4 Procedure

After calibrating the instrument, introduce the sample of the product, record the oxygen content that is displayed by instrument.

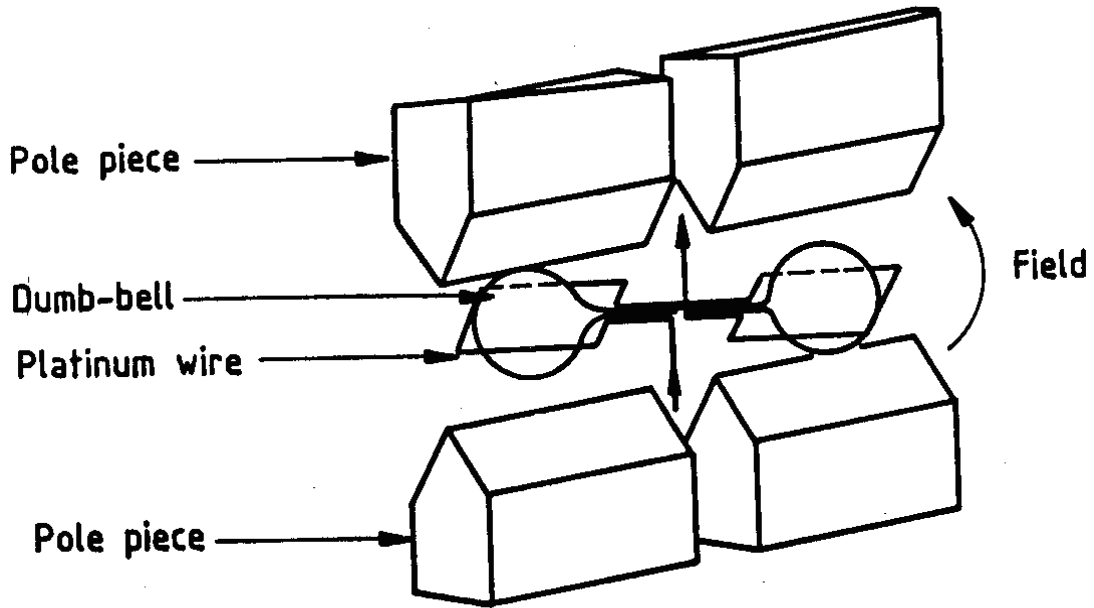


Figure A.2 Measuring Cell Configuration

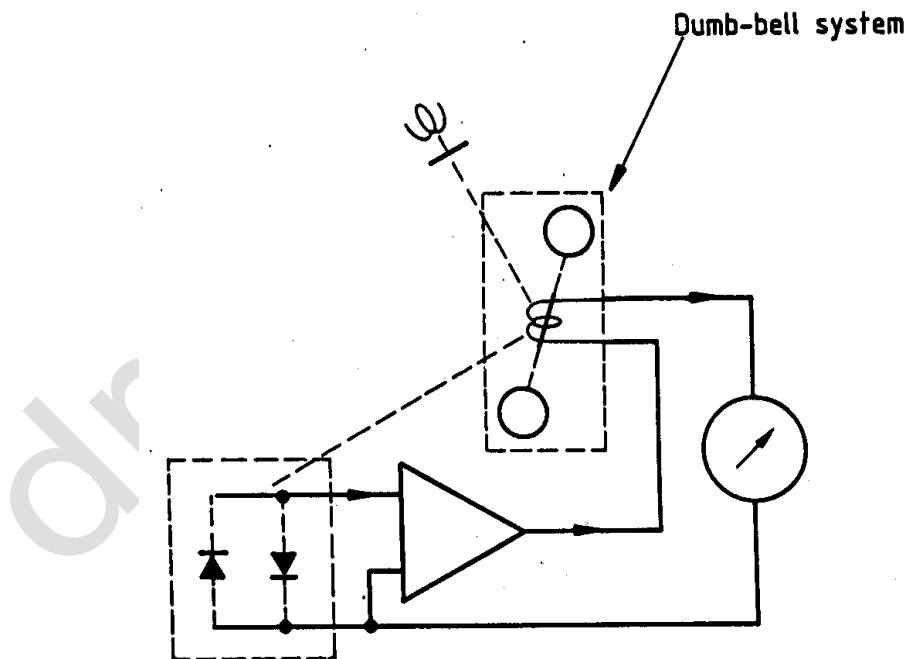


Figure A.3 Typical Analyser configuration (electronic)

Annex B

(Normative)

Determination of moisture (water vapour)

B.1 General

Presence of moisture in oxygen gas shall be determined by dew point or by weight of moisture content. For dew point determination, electrolytic hygrometer, frost or dew point hygrometer, and capacitance hygrometer shall be used. For determination of weight of moisture content, absorption method shall be followed. The procedure to be followed for determining the dew point by hygrometer method shall depend upon type of apparatus to be used and manufacturer's instruction.

B.2 Electrolytic hygrometer

The method is based on absorption and electrolysis if water vapour is present in the sample gas. The electrolytic current gives a direct measurement of water vapour present in the gas flowing through the instrument at steady rate. The exact procedure to be followed shall depend on the type of apparatus to be used. The instrument manufacturer's instruction in this regard shall be followed.

B.3 Frost or dew point hygrometer

A metal surface on the hygrometer is cooled so that dew or frost is formed from the vapour content of the gas at a particular pressure which may be observed optically in the apparatus. The temperature at which the dew or frost is formed is a measure of water vapour content of the gas. The exact procedure to be followed shall depend upon the type of apparatus to be used. The instrument manufacturer's instructions in this regard shall be followed.

B.4 Capacitance hygrometer

The method is based on the change of capacitance of the sensor when a sample gas containing water vapour passes through it. The change in capacitance gives a direct measurement of water vapour present in the gas. The procedure to be followed shall depend on the type of apparatus to be used. The instrument manufacturer's instructions in this regard shall be followed.

B.5 Absorption method

B.5.1 Apparatus

The apparatus consists of the following parts assembled as shown in **Figure B.1.**

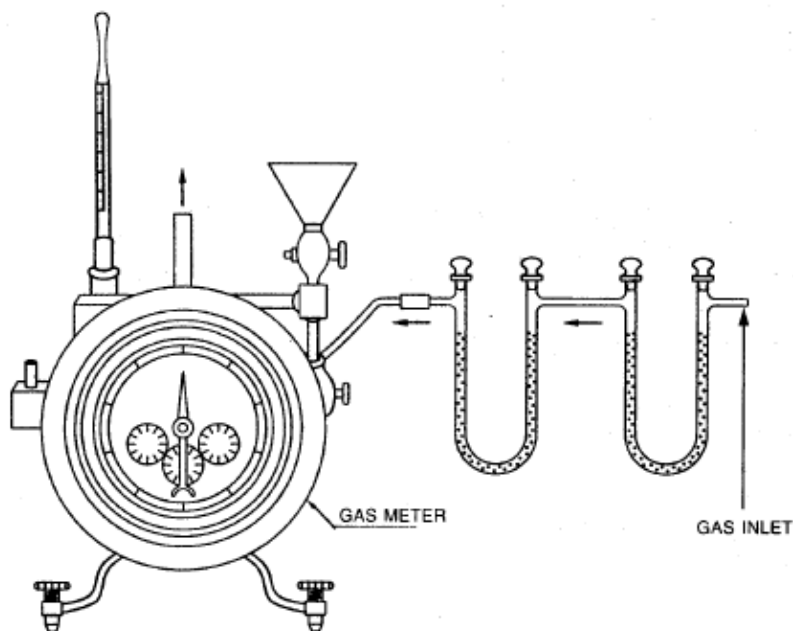


Figure B.1 - Assembly of apparatus for determination of moisture

B.5.1.1 Gas meter, accurate to 1 percent.

B.5.1.2 Absorption Train, three U tubes containing phosphorous pentoxide connected in a series to the gas meter. The one near to the gas meter will serve as a guard to prevent moisture from backing into the first tube.

B.5.2 Procedure

B.5.2.1 Absorption of the moisture from a known volume of oxygen gas by anhydrous calcium chloride (CaCl_2). Or phosphorous pentoxide (P_2O_5) or Silica Gel or mol. Sieve held in a series of U tubes.

B.5.2.2 Quantity of gas flow through U tube train shall be measured by a rotometer or any other type of flow meter having accuracy of not less than ± 5 percent. Flow rate shall be about 500 l/h and not more to ensure complete absorption of oxygen in the hygroscopic chemicals held in the U tube train.

B.5.2.3 U tube train filled with hygroscopic chemicals shall be initially heated to 100°C or more depending on the chemical for 1 h to drive away any moisture absorbed previously by chemicals. The two ends of U tube train shall be firmly closed with rubber stopper not to allow ingress of atmospheric air. Weight of the whole U tube shall be taken on a sensitive chemical balance of accuracy not less than ± 1 percent. The U tube train shall be heated again in two intervals for 15 min each and weighed again after each 15 minutes heating to see that moisture from the chemical has been removed.

B.5.2.4 At least one cylinder full of oxygen gas at full filling pressure having 6 to 7 m^3 of oxygen gas shall be connected to the U tube train through pressure regulator and flow meter. The entire quantity of oxygen gas from the cylinder shall be passed through U tube train at a rate about 500 l/h and when the cylinder is empty, in about 10 h, both ends of the U tube train shall be firmly closed with rubber stopper not to allow any moisture from the air to get in.

B.5.2.5 U tube train after absorption of moisture from oxygen gas shall be weighed in a chemical balance and weight of moisture absorbed from oxygen gas shall be found by the difference in weight of the U tube train before commencement of flow off oxygen and after completion of the flow of oxygen.

B.5.3 Calculation

B.5.3.1 Volume of total oxygen gas flow shall be checked from the flow meter. Alternatively, total quantity of oxygen gas flow can be found out from water capacity of gas cylinder punched on the body of the cylinder and the difference between the initial full pressure of oxygen gas in the cylinder and the final pressure of oxygen in the gas cylinder when flow is stopped. The quantity of gas flow can be found out in the following manner.

The water capacity of gas cylinder punched on the body :X litre
 Pressure of the gas cylinder full with oxygen :P₁ bar
 Pressure in oxygen gas cylinder when flow from cylinder is stopped :P₂ bar

$$\text{Total quantity of oxygen gas flow from cylinder to "U" tube train} = \frac{X \times (P_1 - P_2)}{1000} \text{ m}^3$$

“m³” shall be converted to Nm³ by applying the gas law, $K = \frac{PV}{T}$

If the chemical balance employed for weighing is not sensitive enough, then the gas from more than one oxygen cylinder may be passed to increase absorption of more moisture and thereby to increase the weight of the U tube train for easier weighing.

B.5.3.2 The weight of moisture absorbed in the U tube train in grams divided by the volume of oxygen passed in Nm³, shall show moisture content, in g/Nm³.

B.5.3.3 The above test shall be repeated 3 times and the average moisture content in g/Nm³ shall be determined. This shall not be more than 0.102 g/Nm³ corresponding to -40°C dew point.

Annex C

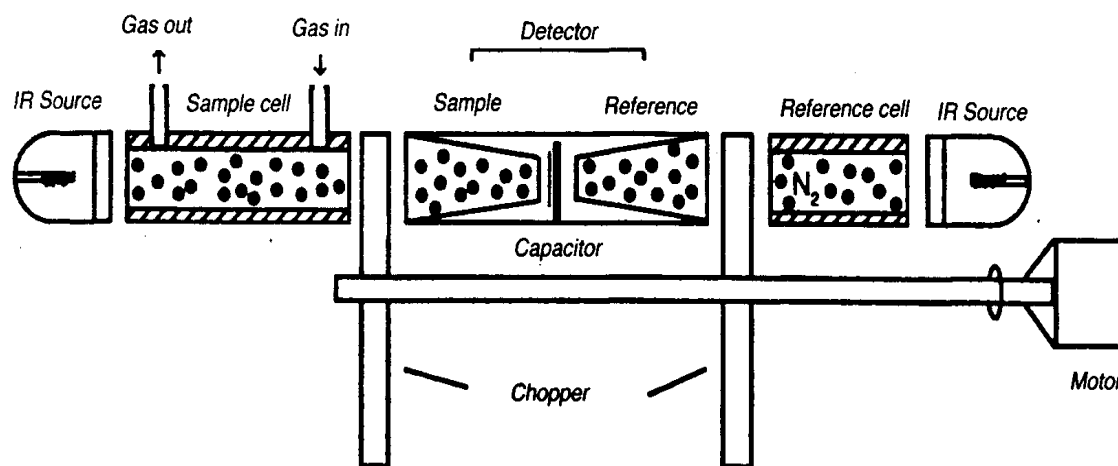
(Normative)

Determination of carbon dioxide based on European Pharmacopoeia

C.1 Principle

Carbon dioxide in medicinal gases is determined using an infrared analyzer (FigureC.1)**C.2 Procedure**

The infrared analyzer includes a system generating two identical infrared beams consisting of coils electrically heated to low red heat equipped with reflectors. One beam crosses a sample cell and the other beam crosses a reference cell. The sample cell receives a stream of gases to be analyzed and reference cell contains nitrogen **R1**. The two chambers of the detector are filled with carbon dioxide **R1** and the radiation is automatically received selectively. The absorption of this radiation produces heat and differential expansion of the gas in the two chambers, owing to absorption of some of the emitted radiation by the carbon dioxide in the gas to be examined. The pressure difference between the two chambers of the detector causes distension of the metal diaphragm that separates them. This diaphragm is part of a capacity, whose capacitance varies with the pressure difference, which itself depends on the carbon dioxide content in the gas to be examined. Since the infrared beams are periodically blocked by a rotating chopper, the electric signal is frequency modulated.



FigureC.1 – Infrared analyzer

Annex D (normative)

Determination of carbon monoxide based on European Pharmacopoeia

D.1 The process of determination of carbon monoxide in medical gases involves two methods

D.2 Method I

D.2.1 Apparatus (Figure C.2)

The apparatus consists of the following parts connected in series:

D.2.1.1 U-tube (U_1) containing anhydrous silica gel R impregnated with chromium trioxide R.

D.2.1.2 Wash bottle (F_1) containing 100 ml of a 400 g/l solution of potassium hydroxide R.

D.2.1.3 U-tube (U_2) containing pellets of potassium hydroxide R.

D.2.1.4 U-tube (U_3) containing diphosphorus pentoxide R dispersed on previous granulated, fused pumice,

D.2.1.5 U-tube (U_4) containing 30 g of recrystallised iodine pentoxide R in granules, previous dried at 200 °C and kept at a temperature of 120 °C (T) during the test. The iodine pentoxide is packed in the tube in 1 cm columns separated by 1 cm columns of glass wool to give an effective length of 5 cm.

D.2.1.6 Reaction tube (F_2) containing 2.0 ml of potassium iodide solution R and 0.15 ml of starch solution R.

D.2.2 Procedure

Flush the apparatus with 5.0 litre of argon R and, if necessary, discharge the blue colour in the iodine solution by adding the smallest necessary quantity of freshly prepared 0.002M sodium thiosulphate. Continue flushing until not more than 0.045 ml of 0.002 M sodium thiosulphate is required after passage of 5.0 litre of argon R. Pass the gas to be examined from the cylinder through the apparatus, using the prescribed volume and the flow rate. Flush the last traces of liberated iodine into the reaction tube by passing through the apparatus 1.0 litre of argon. Carry out blank test, using the prescribe volume of argon R. The difference between the volumes of 0.002 M sodium thiosulphate used in the titration is not greater than the prescribed limit.

D.3 Method II

Carbon monoxide in medicinal gases is determined using an infrared analyzer as detailed in Annex C.

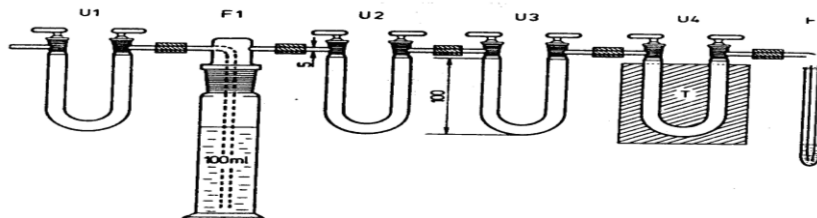


Figure C.2 Apparatus for the determination of carbon monoxide in medicinal gases

Annex E
(Normative)

Determination of volume fraction of hydrocarbons

E.1 Gas Chromatograph with flame ionization detector, gas sampling valve, suitable valve to 'backflash' hydrocarbon to detector shall be used for determination of volume fraction of hydrocarbon. Nitrogen gas shall be used as carrier gas. Instruction of the manufacturer of the instrument shall be followed for calibration and calculation of volume fraction of hydrocarbons in oxygen gas.

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Annex F
(Normative)

Sampling of oxygen gas for medical use

F.1 Procedure

F.1.1 On regular production, two samples selected at random shall be tested per hour of compression.

F.1.1.1 The production shall be declared as conforming to this standard, if the sample passes the requirement stipulated in this standard.

F.1.1.2 However, if the sample fails in the oxygen and moisture content test, then sampling frequency shall be doubled until all samples pass for consecutive 2 h.

draft standard

Annex G
(Informative)
Determination of odour

G.1 Carefully open the container valve to produce moderate flow of gas. Do not direct the gas stream towards the face, but deflect portion of the stream towards the nose: no appreciable odour shall be discernible.

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