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DRAFT UGANDA STANDARD

Second Edition
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Oxygen for medical use — Specification

DRAFT UGANDA STANDARD FOR PUBLIC REVIEW

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Foreword

Uganda National Bureau of Standards (UNBS) is a parastatal under the Ministry of Trade, Industry and Cooperatives established under Cap 327, of the Laws of Uganda, as amended. UNBS is mandated to co-ordinate the elaboration of standards and is

(a) a member of International Organisation for Standardisation (ISO) and

(b) a contact point for the WHO/FAO Codex Alimentarius Commission on Food Standards, and

(c) the National Enquiry Point on TBT Agreement of the World Trade Organisation (WTO).

The work of preparing Uganda Standards is carried out through Technical Committees. A Technical Committee is established to deliberate on standards in a given field or area and consists of key stakeholders including government, academia, consumer groups, private sector and other interested parties.

Draft Uganda Standards adopted by the Technical Committee are widely circulated to stakeholders and the general public for comments. The committee reviews the comments before recommending the draft standards for approval and declaration as Uganda Standards by the National Standards Council.

The committee responsible for this document is Technical Committee UNBS/TC 301, Chemistry.

This second edition cancels and replaces the first edition (US 1511:2014), which has been technically revised.

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Introduction

Oxygen is an essential medicine that is used to treat hypoxaemia at all levels of the health care system. It is required for surgery, acute respiratory illnesses such as severe pneumonia, chronic pulmonary diseases, emergencies and cardiovascular diseases, among others.

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Oxygen for medical use — Specification

1 Scope

This Draft Uganda Standard specifies the requirements, methods of sampling and testing of oxygen for medical use only.

2 Normative references

The following referenced documents referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 32, Gas cylinders for medical use — marking for identification of content

ISO 5145, Cylinder valve outlets for gases and gas mixtures — Selection and dimensioning

ISO 7225; Gas cylinders — Precautionary labels

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
medical oxygen
gaseous or liquid oxygen, having a chemical formula O_2, intended for medical use

3.2
lot
oxygen filled in container of the same type and size at the same period

3.3
body
cylindrical part of a gas cylinder

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at http://www.iso.org/obp

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4 Requirements

4.1 General requirements

4.1.1 Medical oxygen shall be manufactured from a hygienic facility

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4.1.2 Medical Oxygen in gaseous form shall be odourless and colourless. In case of liquid form, it shall be odourless and of a light blue colour.

4.2 Physical and chemical requirements

Oxygen for medical use shall comply with the requirements specified in Table 1 when tested in accordance with the methods prescribed therein.

Table 1 — Physical and chemical requirements

S. No	Characteristic	Requirement	Test method
1	Moisture, mg/dm^3, max.	0.12	Annex A
2	Acidity or alkalinity	Shall pass the test	Annex B
3	Oxidising substance*	Shall pass the test	Annex C
4	Purity by volume, %, min.	99.5	Annex D
5	Carbon dioxide, mm^{3}dm^3, max.	300	Annex E
6	Carbon monoxide, mm^{3}dm^3, max.	5	Annex F
*In case the process is air-liquefaction and use adsorption technique by alumino silicate or activated alumina as carbon dioxide and moisture remover, acidity or alkalinity and oxidizing substance tests are not required.			

5 Packaging

5.1 Containers for medical oxygen shall be clean, free from pollutants and contaminants and shall be used for medical oxygen only.

5.2 Containers in the form of cylinders shall be in accordance with ISO 5145.

5.3 The medical oxygen cylinder shall be white on its neck and shoulder in accordance with ISO 32.

5.4 The medical oxygen cylinder connectors shall be provided with wrapping material to protect against entry of dust and to sort the used cylinders from the unused cylinders. The name and trademark of filler shall be provided on the wrapping material.

6 Labelling

Each container or the attached label shall at least bear a number, letter or mark indicating legibly and clearly the following information:

i) the term "MEDICAL OXYGEN" together with its chemical formula "O_2" written on the container body in white letters of the size not smaller than one-eighth (1/8) of the cylinder diameter;.

ii) name of manufacturer or factory or registered trade mark and packer or distributor with address;

iii) lot identification;

iv) net content at a pressure of 0.1 Mpa and filling pressure in mega Pascals (Mpa) at a temperature of 27^{o}C± 2^{o}C; and

v) safety precaution for use, handling and storage

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7 Storage

7.1 Oxygen shall be kept as compressed gas or liquid at cryogenic temperature, in appropriate containers complying with the safety regulations of the national authority.

7.2 Valves or taps shall not be lubricated with oil or grease.

8 Sampling and criteria for conformity

8.1 Sampling and acceptance shall be in accordance with the sampling plan in 7.2 and 7.3 or its technical equivalent.

8.2 In the case of cylinders, a number of container(s) shall be taken at random in accordance with the plan given in Table 2 for conformity tests on requirements, containers and packaging, and marking and labelling.

Table 2 — Sampling plan

Lot size container	Lot size container
1 - 30	1
31 - 60	2
60 and above	3

8.3 In case of tanks, the sample shall be taken in liquid form from the storage tank and transferred into a Dewar flask or other equivalent vessels in an amount not less than 2 dm^3 for requirement inspection

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Annex A
(normative)

Determination of moisture content

A.1 Apparatus

The apparatus shall be as shown in Figure A.1.

A.2 Reagents

A.2.1 Dry ice

A.2.2 Acetone or ethanol

A.3 Procedure

A.3.1 Pass the sample gas through the inlet tube at a rate of approximately 1dm^{3}min - 5 dm^{3}min. Add acetone or ethanol approximately half of the height into the cylindrical vessel.

A.3.2 Gradually add small pieces of dry ice and stir well until water vapour is formed on the external surface of the cylindrical vessel A at the end of the inlet tube. Immediately read the temperature.

A.3.3 Repeat the test by allowing the temperature to go up until all water vapour disappears. Then repeat A.3.2 until constant temperature is obtained. Provided that the temperature measured is not higher than - 40 ^{o}C, the sample is deemed to have moisture content not exceeding 0.12 mg/dm^3.

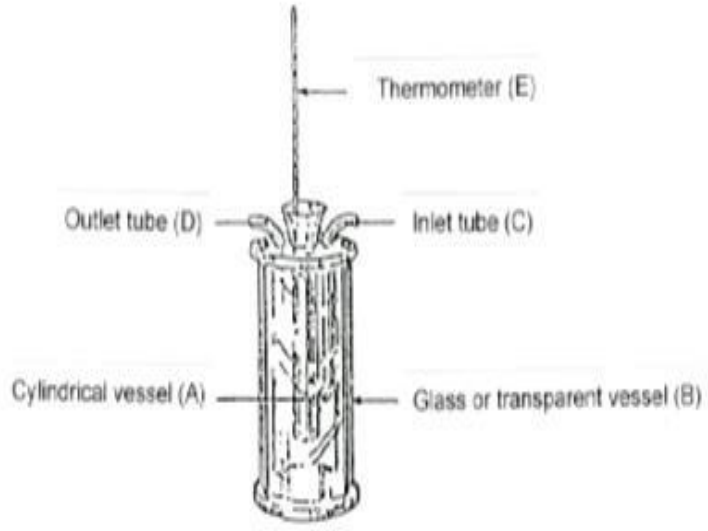

Figure A.1 — Apparatus for analysis of moisture content

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Key

A is a thin-walled cylindrical vessel made of metal, for example copper coated with chromium, with approximately 4-mm diameter and 7.5 cm - 12.7 cm high, the external surface being polished and not causing any difference in temperature at the internal and external surfaces.

B is a glass or transparent vessel with a lid.

C is an inlet tube; made of copper with an orifice of 6 mm. End of tube is approximately 2.5 mm above the bottom of the vessel.

D is an outlet tube, made of copper with an orifice of 6 mm. The other end is connected to gas volume meter.

E is a thermometer capable of reading a temperature below – 40 ^{o}C.

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Annex B
(normative)

Determination of acidity and alkalinity

B.1 Apparatus

B.1.1 **Three glass cylinders** of 30-mm internal diameter and approximately 180 mm in height with stoppers (see Figure B.1). The second cylinder shall be provided with a rubber stopper, fitted with an inlet tube having an orifice of 0.5 mm in internal diameter with length almost reaching the bottom of glass cylinder, and an outlet tube connected to gas volume meter.

B.1.2 **Gas volume meter**

B.2 Reagents

B.2.1 Hydrochloric acid solution, 0.01 mol/dm^3

B.2.2 Methyl red indicator solution, 0.5 by weight. Dissolve 0.5 g of methyl red in 100 dm^3 of distilled water.

B.3 Procedure

B.3.1 Transfer 1cm^3 of methyl red indicator solution into 350 cm^3 of distilled water and heat to boiling for 5 min.

B.3.2 Then transfer the warm solution into three glass cylinders, 100 cm^3 each.

B.3.3 In the first cylinder drop 0.1 cm^3 of hydrochloric acid solution.

B.3.4 In the second and the third cylinders drop 0.2 cm^3 of hydrochloric acid solution.

B.3.5 Stopper the first and the third cylinders and pass 2 dm^3 of the sample gas through the second cylinder within 30 min.

B.3.6 Compare the colour in the three cylinders by placing them on white surface.

B.3.7 Remove the stopper and view the colour from top of the cylinder.

B.3.8 Samples shall be deemed to comply with the specification if colour of solution in the second cylinder is not more yellow than in the first cylinder or pink intensity in the second cylinder is not more than in the third cylinder.

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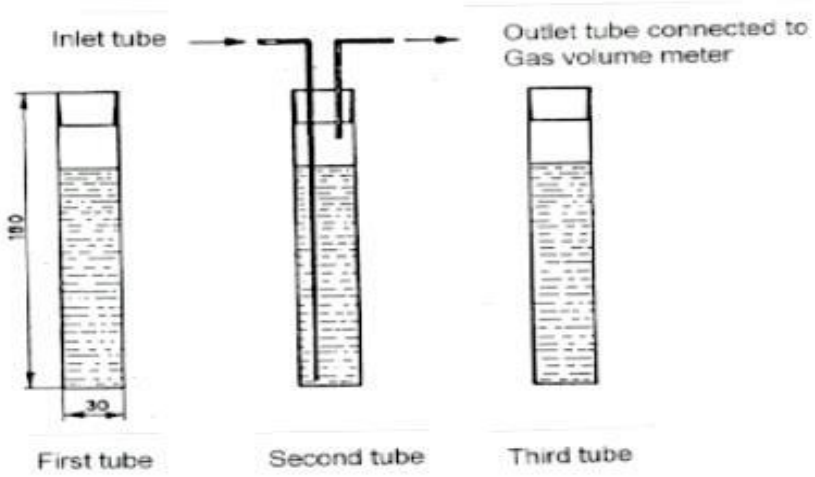

Figure B.1 — Apparatus for analysis of acidity

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Annex C
(normative)

Determination of oxidising substance

C.1 Apparatus

Two glass cylinders, the same as the first and the second cylinders in B.2

C.2 Reagents, solutions and preparations

C.2.1 Glacial acetic acid, of density 1.049 g/cm^3

C.2.2 Potassium iodide-starch solution.

C.2.2.1 Dissolve 0.75 g of potassium iodide in 100 cm^3 of distilled water.

C.2.2.2 Boil and add all starch solution (dissolve 0.5 g of starch in 35 cm^3 of distilled water), then agitate and continue to boil for a few minutes, and allow to cool.

C.2.2.3 Test for solution activity by adding 0.05 cm^3 glacial acetic acid and 0.25 cm^3, 0.5 m mol/ dm^3 iodine into 15 cm^3 of the solution.

C.2.2.4 The solution colour shall be changed into blue.

C.3 Procedure

C.3.1 Add into both cylinders 50 cm^3 of the freshly prepared potassium iodide-starch solution and 0.2 cm^3 of glacial acetic acid.

C.3.2 Pass 5 dm^3 of sample gas through the second cylinder.

C.3.3 Provided the intensity of the solution in the second cylinder is the same as that of the first, the sample is deemed to have passed the test.

Note: The test shall be carried out at a place not being exposed to light.

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Annex D
(normative)

Determination of purity

D.1 Apparatus

It shall be as shown in Figure D.1.

D.2 Reagents and preparation

D.2.1 Ammonium chloride-ammonium hydroxide solution.

D.2.1.1 Dissolve 550 g of ammonium chloride in 1250 cm^3 of water and

D.2.1.2 add 750 cm^3 of concentrated ammonium solution, with density of 0.88 g/cm^3.

D.3 Procedure

D.3.1 Assemble the apparatus (Figure D.1) with tube ends connection.

D.3.2 Put a suitable amount of ammonium chloride-ammonium hydroxide solution into the absorption pipette and the levelling bottle.

D.3.3 Exhaust the air in the burette, the absorption pipette and stopcock C, and then allow the sample gas into the absorption pipette until a volume of 100 cm^3 is obtained

D.3.4 Drive the gas back and forth between the burette and the absorption pipette until constant volume of gas in the burette is obtained

D.3.5 The lost volume of gas in the burette is the purity of the sample gas in percentage by volume. Newly prepared ammonium chloride-ammonium hydroxide solution shall be a few times subjected to trial oxygen analysis prior to the actual analysis. The solution can be used several times unless poor oxygen absorption and formation of sediment is presented.

NOTE The absorption pipette should be always filled with copper.

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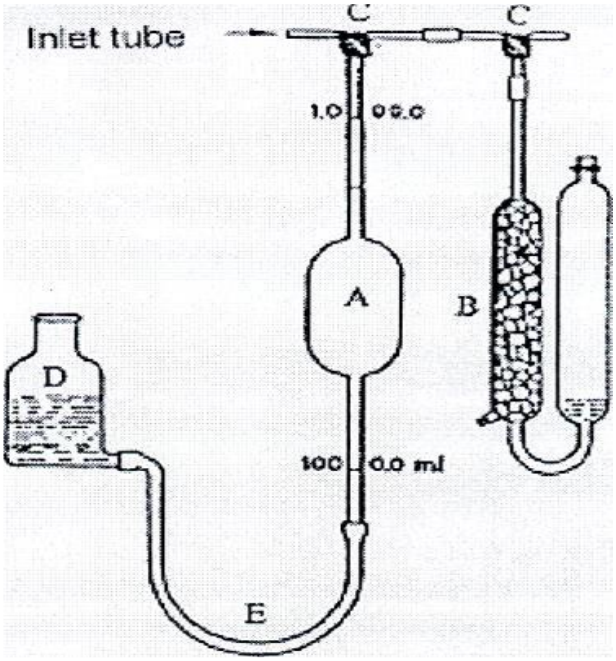

Figure D.1 — Apparatus for analysis of purity

Key

A is a burette of 100 cm^3 capacity, and scales from 99 cm^3 - 100 cm^3 having scale readable to 0.1 cm^3

B is an absorption pipette fully containing copper wire spirals, bars or fragments inside

C is three-way capillary stopcock with an orifice of 1mm. internal diameter

D is levelling bottle of 175cm^3 capacity

E A rubber hose of approximately 750 mm long connected to the burette, A, and levelling bottle, D

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Annex E
(normative)

Determination of carbon dioxide

E.1 Apparatus

E.1.1 Carbon dioxide detector tube

E.1.2 Gas volume meter

E.2 Procedure

E.2.1 Pass 1dm^3 of sample gas through the carbon dioxide detector tube, connected to the gas volume meter, the calibration of which is verified according to the manufacturer's instructions, at the speed specified on each individual type.

E.2.2 Read the obtained value from the detector tube

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Annex F
(normative)

Determination of carbon monoxide

F.1 Apparatus

F.1.1 Carbon monoxide detector tube

F.1.2 Gas volume meter

F.2 Procedure

F.2.1 Pass 1dm^3 of sample gas through the carbon monoxide detector tube, connected to the gas volume meter, the calibration of which is verified according to the manufacturer's instructions, at the speed specified on each individual type.

F.2.2 Read the obtained value from the detector tube.

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[1] TIS 540-2545 (2002), Thai Industrial Standard for medical use.

[2] US 1511: 2014, Oxygen for medical use — Specification

[3] 6.1.260.Oxygen-(Oxygenium)

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