ICS 71.100.20
G86

GB

National Standard of the People's Republic of China

GB/T ×××× — ××××
Replaces GB 8982-1998, GB 8983-1998

Gaseous breathing oxygen supplies for medicines and aircrafts

(2nd Version Submitted for Examination)
(Completed on: 2 February 2008)

Issue Date ××××-××-×× Implementation Date: ××××-××-××

Issued by: **General Administration of Quality Supervision, Inspection and Quarantine of The People's Republic of China (AQSIQ)**

Standardisation Administration of the People's Republic of China (SAC)

Foreword

This Standard replaces GB 8982-1998 “Medical supplies for oxygen” and GB 8983-1998 “Medical supplies for aircraft,” and revises and combines GB 8982-1998 and GB 8983-1998.

In comparison with GB 8982-1998 and GB 8983-1998, the major changes to this Standard are as follows:

— name amended to “Gaseous breathing oxygen supplies for medicine and aircraft”;

— scope of application expanded, increased hose-transported oxygen supplies for aircraft items (Subsection 1 of this Standard);

— normative references adjusted (Subsection 2 of this Standard, Subsection 2 of GB 8982-1998 and Subsection 2 of GB 8983-1998);

— requirements for the contents of total hydrocarbon and solid substance increased, as well as their test methods (Table 1, Subsections 5.7 and 5.8 of this Standard);

—technical indicators of carbon monoxide and carbon dioxide in oxygen for medicine have been revised, as well as their test methods (Table 2 and Subsections 5.3 of this Standard, and Subsections 2, 5.3 and 5.4 of GB 8982-1998);

— technical indicators of carbon monoxide and carbon dioxide in oxygen for aircrafts increased, as well as their test methods (Table 2 and Subsections 5.3 and 5.4 of this Standard);

—sampling, judgment and re-inspection have been revised (Subsection 4 of this Standard, Subsection 4 of GB 8982-1998, and Subsection 5 of GB 8983-1998);

Table 1 in this Standard is mandatory.

The Annex of this Standard is a normative Annex.

This Standard was proposed by the China Petroleum and Chemical Industry Association.

The National Gas Standardisation Technical Committee implemented this Standard.

The main drafting units of this Standard are:

The main drafters of this Standard are:

This Standard replaces the former issues GB 8982-1988, GB 8983-1988, GB 8982-1998 and GB 8983-1998.

Gaseous breathing oxygen supplies for medicine and aircraft

1 Scope

This Standard specifies the technical requirements, test methods, packaging, marking, storage and transportation for gaseous breathing oxygen supplies for medicines and aircrafts. This Standard applies to bottled and hose-transported gaseous oxygen supplies for medicines and liquid oxygen supplies for medicines extracted by air separation and water electrolysis, as well as gaseous breathing oxygen supplies for aircrafts and liquid breathing oxygen supplies for aircrafts extracted by cryogenic air separation. These supplies are mainly used as mixed breathing gas for medicines, for divers, the breathing of aircraft aviators, etc.

Molecular formula: O_2.

Relative molecular mass: 31.9988 (calculated according to the International Relative Atomic Mass of 2005).

2 Normative references

The provisions of the following documents become provisions of this Standard after being referenced. For dated reference documents, all later amendments (excluding corrigenda) and versions do not apply to this Part; however, the parties to the agreement are encouraged to study whether the latest versions of these documents are applicable. For undated reference documents, the latest versions apply to this Standard.

GB/T 3835 Industrial oxygen

GB/T 5832.2 Determination of trace water in gases — Dew point method

GB/T 8984.1-1997 Determination of carbon monoxide, carbon dioxide and hydrocarbon in gases — Part 1: Determination of carbon monoxide, carbon dioxide and methane in the gases — Gas chromatographic method

GB/T 8984.3-1997 Determination of carbon monoxide, carbon dioxide and hydrocarbon in gases — Part 3: Determination of total hydrocarbon in gases — Flame ionisation method.

3 Requirements

3.1 The total pollutants in gaseous breathing oxygen supplies for medicines and aircrafts should produce no toxicity toward the user.

3.2 The technical requirements for gaseous breathing oxygen supplies for medicines should meet the requirements set out in Table 1.

3.3 The technical requirements for gaseous breathing oxygen supplies for aircrafts should meet the requirements set out in Table 2.

Table 1 Technical requirements for gaseous breathing oxygen supplies for medicines

Item		Indicator
Oxygen (O_2) content (volume fraction) / 10^{-2} •		99.5
Water (H_2O) content (dew point) / ^oC •		– 43
Carbon dioxide (CO_2) content (volume fraction) / 10^{-6} •		100
Carbon monoxide (CO) content (volume fraction) / 10^{-6} •		5
Content of gaseous acidic substance and alkaline substance		Passed the inspection according to the specified methods
Contents of ozone and other gaseous oxides		Passed the inspection according to the specified methods
Odour		No peculiar odour
Total hydrocarbon content (volume fraction) / 10^{-6} •		60
Solid substance	Grain •	100• m
	Content, mg/m^3 •	1
Note: No requirement is specified for odour, water content and solid substance of liquid oxygen.		

Table 2 Technical requirements for gaseous breathing oxygen supplies for aircrafts

Item		Indicator
Oxygen (O_2) content (volume fraction) / 10^{-2} •		99.5
Water (H_2O) content (dew point) / ^oC •		– 65
Carbon dioxide (CO_2) content (volume fraction) / 10^{-6} •		100
Carbon monoxide (CO) content (volume fraction) / 10^{-6} •		5
Odour		No peculiar odour
Total hydrocarbon content (volume fraction) / 10^{-6} •		60
Solid substance	Grain •	100• m
	Content, mg/m^3 •	1
Remarks: No requirement is specified for the odour, water content and solid substance of liquid oxygen.		

4 Sampling, judgment and re-inspection

4.1 The Quality Inspection Department of the manufacturer is responsible for the

ex-factory inspection of gaseous breathing oxygen supplies for medicines and aircrafts, for issuing certification that the product has passed a quality inspection, and for guaranteeing that all ex-factory gaseous breathing oxygen supplies for medicines and aircrafts meet the requirements of this Standard and are traceable. This department of the manufacturer should be responsible for the quality of products.

4.2 The manufacturing factory should take one batch of products to mean gaseous breathing oxygen supplies for medicines and aircrafts that were produced in one operational shift or produced at the same time as a batch of products. The user should take a batch of products to mean the quantity carried by the same lorry or purchased in the same lot. According to the requirements set out in Table 3, a random sampling inspection should be made for each batch. If any single indicator in the inspection result does not meet the requirements set out in this Standard, a double quantity of random samples should be taken from the same batch of products, in order for a re-inspection to take place. If any item still does not meet the requirements set out in this Standard, the concerned batch of products shall be regarded as non-conforming.

Table 3 Sampling table

Product batch (bottle)	1	2~8	9~15	16~25	26~50	• 51
No of samples (bottle)	1	2	3	4	5	6

4.3 For hose-transported oxygen, a sampling inspection should be performed once within 4 hours. If any single item does not meeting the requirements of this Standard in the inspection results, the product shall be regarded as non-conforming within these 4 hours.

4.4 The inspection of liquid oxygen supplies should be carried out after the liquid sample taken from each storage container has evaporated. If any single item does not meet the requirements of this Standard in the inspection results, the product shall be regarded as non-conforming.

4.5 The sampling safety of gaseous breathing oxygen supplies for medicines and aircrafts should meet the related requirements of GB/T 3863.

5 Test methods

5.1 Test for oxygen content in gaseous breathing oxygen supplies for medicines and aircrafts

This test should be carried out according to the requirements set out in GB/T 3863.

5.2 Test for water content in the gaseous breathing oxygen supplies for medicines and aircrafts

This test should be carried out according to the requirements set out in GB/T

5832.2.

5.3 Test for carbon monoxide and carbon dioxide content in gaseous breathing oxygen supplies for medicines and aircrafts

5.3.1 Adopt the gas chromatograph with cutting procedures, methanation converter and hydrogen flame ionised detector (FID) to test the content of carbon monoxide and carbon dioxide. Test limit: 0.1×10^{-6}.

5.3.2 The principles and general requirements conform to the stipulations of GB/T 8984. After the samples have been prepared, the oxygen signal should be cut off first.

5.4 Test for gaseous acidic substance and gaseous alkaline substance in the breathing oxygen supplies for medicines

5.4.1 Reagents and solutions

— Distilled water or deionised water;

— Hydrochloric acid solution: 0.01mol/l;

— 60×10^{-2} ethanol solution;

— 20×10^{-2} ethanol solution;

— Methyl red indicator: 0.2×10^{-2} ethanol solution, which is made by dissolving 0.2g of methyl red in 100ml of ethanol (60×10^{-2}) solution;

— Bromothymol blue indicator: 0.1×10^{-2} alcohol solution, which is made by dissolving 0.1g of bromothymol blue in 100mL of ethanol (20×10^{-2}) solution.

5.4.2 Instruments

— Graduated pipette: 1mL in capacity;

— Munsell gas washing bottle: 100mL in capacity;

— Gas discharge meter;

— Measuring cylinder: 100mL in capacity.

5.4.3 Tests

Use a hose to connect the depressurized gaseous breathing oxygen supplies for medicine with the gas washing bottle and gas discharge meter. Open the gas sample to blow off the washing bottle for 1 min. ~ 2 min.

Add 0.3mL of methyl red indicator and 0.3mL of bromothymol blue indicator into 400mL of distilled water. Boil it for 5 min., and then cool it down under room temperature. Pour 100mL of it into each of the three gas washing bottles, No.1, No. 2 and No.3.

Use a pipette to add 0.20mL of hydrochloric acid solution (0.01mol/L) into Bottle No. 2, and add 0.40mL of hydrochloric acid solution (0.01mol/L) into Bottle No. 3.

Within 30min. ~ 35min., let 2000mL of oxygen pass through the solution inside Bottle No. 2.

Compare the solution colour of Bottle No. 2 with the solution colours of Bottle Nos. 1 and 3. If the solution colour of Bottle No. 2 is not darker than the solution colour of Bottle No. 1, it is judged that the gaseous alkaline content in the gaseous breathing oxygen supplies for medicine meets the requirements. If the solution colour of Bottle No. 2 is lighter than the solution colour of Bottle No. 3, it is judged that the gaseous acid content in the gaseous breathing oxygen supplies meets the requirements.

5.5 Tests of ozone and other gaseous oxides in the gaseous breathing oxygen supplies for medicine

5.5.1 Reagents and solutions

— Distilled water or deionized water;

— Acetic acid: Analytically pure.

— Potassium iodide: Analytically pure.

— Soluble starch: Analytically pure.

— Blended liquid of starch and potassium iodide: Dissolve 0.5g of potassium iodide in 95mL of heated water. After starch is blended with 5mL of cold water, the solution is stirred and poured slowly into the boiling potassium iodide solution. Boil the blended liquid for 2 min. ~ 3 min.

5.5.2 Instruments

— Graduated pipette: 1mL in capacity;

— Munsell gas washing bottle: 100mL in capacity;

— Gas discharge meter;

— Measuring cylinder: 100mL in capacity.

5.5.3 Tests

Use a hose to connect the depressurised gaseous breathing oxygen supplies for medicine with the gas washing bottle and gas discharge meter. Open the gas sample to blow off the washing bottle for 1 min. - 2 min.

Pour 100ml of the newly blended solution of starch and potassium iodide into the gas washing bottle, and add in 1 drop of acetic acid.

Allow 2000ml of oxygen to pass through the gas washing bottle within 30-35min.

Observe the solution inside the gas washing bottle. If it remains colourless, then the inspection of ozone and other gaseous oxides is deemed to be passed.

5.6 Odour test in the gaseous breathing oxygen supplies for medicine

To carry out the odour test, make a small opening in the bottle valve and use the nose to smell the contents: no peculiar odours should be emitted.

5.7 Test for total hydrocarbon content in gaseous breathing oxygen supplies for medicines

This test is performed according to Subsection 3 of GB 8984.3-1997.

5.8 Test for solid substances in gaseous breathing oxygen supplies for medicine

5.8.1 Method

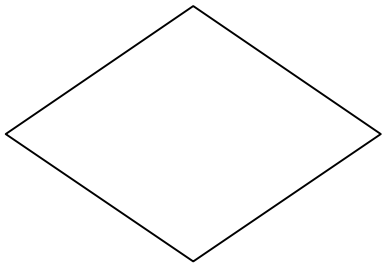
This test is carried out using the filter-paper sampling weighing method. Allow a certain volume of the sample to pass through the powder and dust collector with filter paper. Based on the volume of the gas sample having passed through the filter paper, and the difference in mass before and after the gas passes through the filter paper, the contents of solid substance can be calculated. The grain size is measured using a microscope.

5.8.2 Instruments and materials

— Accumulated gas discharge meter;

— Powder and dust collector, as shown in Figure 1;

— Filter paper: extremely fine glass-fibre filter paper or polypropylene synthetic-fibre filter paper. After the gas has passed through the filter paper, there should be no solid substance greater than 1• m (1• m inclusive) found in the gas.



1 – filter paper;
2 – metal net;
3 – filter paper clamper

Figure 1 Powder and dust collector

5.8.3 Preparation before analysis

Wash the powder and dust collector and allow it to dry.

Cut the filter paper into a circular shape and weigh it (accuracy to 0.1mg). Next, place it in the filter paper clamper. Prevent any powder, dust or other impurities (e.g. water) from coming into contact with the weighed filter paper.

Use a hose free of powder, dust or water to correctly connect the steel bottle holding the sample, the powder and dust collector as well as the discharge metre.

5.8.4 Analysis

Open the steel bottle containing the gas sample. Adjust the discharging speed within the rated value of the discharge meter.

After the gas sample has passed through the filter paper for over $1m^3$, remove the filter paper and weigh it (accuracy to 0.1mg). The difference between the relative humidity of the balance room and the relative humidity of filter paper measured at the first time should not exceed 100×10^{-2}.

5.8.5 Calculating the result

Calculate solid substances in the oxygen according to equation (1):

$$X_1 = \frac{m_2 - m_1}{V} \quad \text{..... (1)}$$

In the equation:

X_1 — content of solid substance, mg/m^3;

m_1 — mass of filter paper before taking sample, mg;

m_2 — mass of filter paper after taking sample, mg;

V — volume of sample converted to be under 15°C and 101.3kPa, m^3.

5.9 Test of the grain size of solid substances

Place the weighed filter paper indicated in Subsection 5.8 under a microscope for 40 times magnification. Observe the filter paper; there should be no grains greater than 100• m.

6 Packaging, marking, storage and transportation

6.1 General requirements

6.1.1 The general requirements for the packaging, storage, transportation and marking of gaseous breathing oxygen supplies for medicines and aircrafts should be implemented according to the related requirements set out in GB/T 3863.

6.1.2 This Standard forbids the use of fluoroplastics or other materials that have not passed the inspection made by the medical supervision authorities in the production of piston-sealed compressors to carry out the compressed filling or pressurised transportation.

6.1.3 Regarding the filling facilities for gaseous breathing oxygen supplies for medicines and aircrafts: there should be a dedicated package container, transportation channel, warehouse etc., all of which must clearly indicate that the oxygen is for medical-use. It is forbidden to use any container that originally held any other gas to hold gaseous breathing oxygen supplies for medicine.

6.1.4 The locations for the filling, storage and use of gaseous breathing oxygen supplies for medicines and aircrafts should be well-ventilated. Strictly monitor and control the oxygen content of the worksite at below 23%.

6.1.5 The production enterprise should implement bar code information management for gaseous breathing oxygen supplies for medicines and aircrafts, and establish the records and files for each link, such as filling, inspection, delivery, etc., so as to enable the traceability of the safety, quality, etc. of the gaseous breathing oxygen supplies for medicines and aircrafts.

6.2 Filling

6.2.1 The filling safety manager and filing operator of the gaseous breathing

oxygen supplies for medicines and aircrafts should possess professional knowledge, and hold the certificates of special equipment operator.

6.2.2 Before filling, the outer surface of all containers should be individually cleaned and inspected. Ensure the remaining gas and pressure, water pressure period, mark, indication, etc. If the gas bottle comes under any of the following circumstances, filling is strictly prohibited:

— The steel seal mark, colour mark, or the marking of the gaseous breathing oxygen supplies for medicines and aircrafts do not meet the requirements;

— The amboceptor of contents is not confirmed, or there is no remaining pressure;

— The deadline for the water pressure test of the bottle has expired;

— It is oil stained;

— Damage is obviously visible on the gas bottle and further inspection is required. The attachments are incomplete or partly damaged.

6.2.3 For new storage containers or those with no remaining pressure, once the water pressure test has been passed and before being filled with gaseous oxygen for the first time, the bottle must be evacuated, dried and displaced.

6.2.4 Gaseous breathing oxygen supplies for medicines and aircrafts should be filled using a reliable hose, and should not be mixed up with the filling of industrial gas.

6.2.5 The filling of liquid breathing oxygen supplies for medicines and aircrafts should meet the requirements of the corresponding low-temperature container. Excessive filling is strictly forbidden. The filled volume is weighed in mass. The weighing balance should pass standard inspections.

6.2.6 When gaseous breathing oxygen supplies for medicine and aircraft are subjected to circumstances of 20^{o}C and 101.3kPa, the volume should be calculated according to the method specified in Annex B of GB/T 3863.

6.2.7 Upon the completion of filling, the package container should be carefully inspected for any leakages, and to check whether the outer surface is clean and has no dirt. The mouth of the gas bottle should be sterilised and a bottle cover and bottle cap should be fitted (with the exception of containers with a protective shell) and anti-vibration ring (with the exception of bulk packaging).

6.2.8 The inspection record before filling, the filling operation record, and the inspection and re-inspection records after filling should be completely kept safely for future reference. The contents of all records should include at least: container code, capacity, filled volume, filling batch, abnormality, filling date, inspector, and the name or code of filler, etc.

6.3 Storage, transportation and marking

6.3.1 The gaseous breathing oxygen supplies for medicine and aircraft should be stored in the designated warehouses. Empty bottles and filled bottles should be tidily stored in separated zones indicated as such with clear markings.

6.3.2 Gaseous breathing oxygen supplies for medicines and aircrafts stored in warehouses should be clearly indicated with these words, “breathing oxygen for medicine,” “breathing oxygen for aircraft.” The warehouse should be ventilated, dry, free of oil stains, and there should be no direct sunlight. The ground is strictly restricted from being paved with asphalt. There should be no ditch and secret tunnel on the ground. The number of stored bottles should meet the related safety requirements.

6.3.3 In the locations for the storage, transportation and use of gaseous breathing oxygen supplies for medicine and aircraft, there should be no appearance of any naked fire, heat source or fire source. Obvious warning signs should be clearly displayed.

6.3.4 The gaseous breathing oxygen supplies for medicines and aircrafts should not be co-stored or co-transported with any other gases, such as industrial gas, combustible and inflammable substance, toxic substance, corrosive substance, radioactive substance, and so on. In summer, the transportation should be attached with the facilities sheltering from sunshine, and the exposure to sunlight should be avoided.

6.3.5 The bottles of gaseous breathing oxygen supplies for medicines and aircrafts should be placed and arranged tidily. When placed vertically, they should be fixed well to prevent them from falling. When placed horizontally, their top-sides should all face in the same direction.

6.3.6 The transportation of gaseous breathing oxygen supplies for medicins and aircrafts by vehicle (ship) should avoid the daytime period and the city centre locations. The carriers are restricted from being parked or anchored around prosperous city areas and densely populated districts. The transportation should strictly comply with the requirements of Dangerous Goods Transportation Regulations.

6.3.7 The gaseous breathing oxygen supplies for medicines and aircrafts should be lightly filled and lightly placed. Any throwing, sliding, rolling or bumping of them is prohibited.

6.3.8 The locations of gaseous breathing oxygen supplies for medicines and aircrafts should be prepared with sufficient water, fire-fighting equipment and safe passage for the entrance and exit of fire engines and fire fighters.

6.3.9 On the storage and transportation containers of gaseous breathing oxygen supplies for medicine and aircraft, the following words should be clearly indicated:

“breathing oxygen for medicine,” “breathing oxygen for aircraft.”

6.3.10 The validity of gaseous breathing oxygen supplies for medicine and aircraft is normally 1 year.

6.3.11 All safety warnings should meet the related requirements of GB/T 3863.