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**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY/T 1468-2016

**Oxygen concentrator supply systems for use with medical gas
pipeline systems
(English Translation)**

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Foreword

All technical contents of this standard are mandatory:

This standard is drafted in accordance with the rules given in GB/T 1.1-2009:

This standard uses the redrafted method to revise and adopt ISO 10083:2006 "Oxygen concentrator gas supply system for medical gas pipeline system System":

The technical differences between this standard and ISO 10083:2006 and their reasons are as follows:

--- Regarding the normative reference documents, this standard has made adjustments with technical differences to adapt to the technical conditions of our country and the situation of the adjustments the situation is reflected in Chapter 2 "Normative References", and the specific adjustments are as follows:

- Add normative references to GB 50751-2012 (see 4.4, 5:12, 7:1:1, 12:6);
- Add normative reference document WS1-XG-008-2012 (see 4.5:1, 10:3:4:2:2);
- Replace ISO 21969 (see 5.5:4) with YY/T 1440 (YY/T 1440-2016, ISO 21969:2009, MOD);
- Replace ISO 5145 (see 5.5:5) with GB 15383 (GB 15383-2011, ISO 5145:2004, NEQ);
- Replace ISO 10524-2 (see 6.7) with YY/T 1439.2 (YY/T 1439.2-2016, ISO 10524-2:2005, MOD);

--- Deleted the related content of bottle filling (4:6, 7:3:1i in ISO 10083:2006), item 4, item 6 and Appendix J in 11:2:

--- According to the relevant requirements of WS1-XG-008-2012, the content of the oxygen-enriched air (93%) index in Table E:1 has been modified:

This standard makes the following editorial changes to ISO 10083:2006:

- Add relevant instructions in the second paragraph of the introduction;
- Delete or modify part of the content related to "country or region" in ISO 10083:2006;
- Corrected the editorial errors in ISO 10083:2006 (see Figure A:2);
- The international standards involved in the references have been adopted as national standards and industry standards: This standard is based on the corresponding national standards Standards and industry standards are used as references, and the order of references is adjusted:

Please note that some contents of this document may refer to patents: The issuing agency of this document assumes no responsibility for identifying these patents:

This standard was proposed by China Food and Drug Administration:

This standard is under the jurisdiction of the National Anesthesia and Respiratory Equipment Standardization Technical Committee (SAC/TC116):

This standard was drafted: Shandong Shangjian Medical Technology Co., Ltd., Shanghai Medical Device Testing Institute:

Introduction

This standard is used to specify the oxygen concentrator gas supply system that supplies oxygen-enriched air (93% oxygen) to the medical gas pipeline distribution system (such as medical Molecular sieve oxygen generation system) minimum requirements for safety and performance: Specifies the minimum oxygen concentration for the gas produced by the oxygen concentrator gas supply system:

Oxygen concentrators can be used to deliver enriched oxygen as a substitute for medical oxygen (such as "oxygen" in the Chinese Pharmacopoeia) to the medical gas pipeline system Air (93% oxygen), oxygen-enriched air (93% oxygen) is called "oxygen93percent" in the US Pharmacopoeia, that is, "oxygen 93%", and in the European Pharmacopoeia it is called "oxygen (93percent)", that is, "oxygen (93%)", and the oxygen concentrator can be used with a gas supply source containing 100% medical oxygen (ie: oxygen cylinders or cryogenic containers) in combination:

According to the characteristics of the oxygen concentrator and the supply flow rate, the oxygen concentrator can supply products whose oxygen concentration changes within the specified range:

Good quality:

The decision to use oxygen-enriched air (93% oxygen) should be made at an early stage by the health care facility and is outside the scope of this standard: Whether to use rich Oxygen air (93% oxygen) and oxygen mixtures are also determined by the health care facility: The use of gas supply systems that include oxygen concentrators may require national Authority approval:

This standard should not be considered as an endorsement or recommendation for another oxygen concentration:

Gas supply systems with oxygen concentrators can be installed at the time of piping distribution system installation or as a replacement or addition to an existing gas supply system add: A gas supply system with an oxygen concentrator can be supplied as a package and can be installed by a third party: In this case, when connecting the air supply

the manufacturer of the oxygen concentrator gas supply system must provide the installer with suitable instructions for installation and testing of the system to the piping distribution system and prior to use:

when data:

The purpose of this standard is to ensure that:

- Oxygen concentrator gas supply system is properly introduced into health care institutions;
- The quality of oxygen-enriched air (93% oxygen) delivered by the air supply system;
- Continuous supply of oxygen-enriched air (93% oxygen);
- Use suitable materials;
- Cleaning of components;
- Install correctly;
- Provide appropriate control, monitoring and alarm systems for the gas supply system;
- Testing, commissioning and proof:

This standard is intended for use by those concerned with the design, construction, inspection or operation of health care facilities: those involved in the design, manufacture, calibration or testing of Personnel attempting to connect equipment to piping systems fed by oxygen concentrator gas supply systems should also be aware of the contents of this standard:

Appendix J contains rationale for some of the requirements of this standard: Further explanation of the rationale for the requirements and recommendations contained in this standard is provided:

Clauses marked with * after the clause number correspond to principles in Appendix J: The rationale for such requirements not only facilitates the correct use of this standard it can be used and can simplify subsequent modification:

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for medical gas piping systems Oxygen concentrator gas supply system

1 Scope

1.1

This standard specifies the oxygen concentration used in medical gas pipeline distribution systems that meet the requirements of ISO 7396-1 or GB 50751-2012:

The design and installation requirements of the compressor air supply system: