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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

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Steam sterilizer - Performance requirements for biosafety

压力蒸汽灭菌器 生物安全性能要求

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1 Scope

YY 1277 sets the biosafety performance requirements for steam sterilizers, the autoclaves used to make infectious waste and contaminated equipment safe. This is the reverse of ordinary sterilization: the load is dangerous going in, so the standard is concerned with containment as much as with lethality, covering the exhaust and its filtration, the effluent, the door interlocks that prevent an incomplete cycle being opened, and the validation of the cycle against a biological challenge. Autoclaves of this kind serve biosafety laboratories, tuberculosis and infectious disease units and the waste streams of every hospital. Being a YY standard without the /T suffix, compliance is compulsory in China. The 2023 edition takes effect in September 2026. For a manufacturer, this is the text a Chinese registration is assessed against.

This document specifies the biosafety performance requirements for pressure steam sterilizers (hereinafter referred to as sterilizers) and describes the corresponding test methods. This document applies to the sterilization of materials, instruments, utensils, culture media, waste and other items for the purpose of biosafety, so as to prevent the contamination of personnel, animals, plants or the environment by pathogenic factors

transmitted by aerosols and other means. The sterilizers specified in this document are generally used in laboratories or other places with biosafety requirements and biosafety level II or above. This document does not specify safety requirements related to the risk range of use, nor does it specify requirements for validation and routine control of moist heat sterilization. This document is not applicable to the sterilization of confined liquids.

2 Normative references

The provisions of the following documents constitute the essential clauses of this document through normative references in this text. Among them, for referenced documents with dates, only the versions corresponding to the dates are applicable to this document; for referenced documents without dates, the latest versions (including all amendments) are applicable to this document.

GB 18281.3 Sterilization of health care products - Biological indicators - Part 3: Biological indicators for moist heat sterilization processes

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 biosafety The hazards or potential risks caused by various biological factors to the country, society, economy, people's health and ecological environment.

3.2 containment area Areas with relatively high biological risks, where the airtightness of the enclosure structure, airflow, personnel entry, and individual protection are controlled.

3.3 non-containment area Areas with relatively low biological risks, which also refer to areas outside the containment area.

4 Requirements

4.1 Double door interlock Double-door sterilizers shall be equipped with double-door interlocking devices. In normal use, the double doors cannot be unsealed at the same time. After the door on the containment area side is unsealed, an effective sterilization cycle shall be carried out before the door on the non-containment area side can be unsealed.

4.2 Instruments and display devices

4.2.1 For sterilizers used in laboratories or other places with a biosafety level of level 3 or 4, the sterilization chamber pressure gauge and pressure sensor shall be of diaphragm type.

4.2.2 The display device on the non-containment area side of the double-door sterilizer shall be able to display the cycle operation status.

4.3 Control system The use authority of the control system shall be managed at level three

or above.

4.4 Alarm

4.4.1 Abnormal alarm of exhaust gas filter For sterilizers used in laboratories or other places with a biosafety level of level 3 or 4, the manufacturer shall specify the range of pressure difference between the front and rear ends of the exhaust gas filter; when the pressure difference between the front and rear ends exceeds or falls below the set value, the sterilizer shall alarm.

4.4.2 Abnormal alarm of external utility facilities

4.4.2.1 The manufacturer shall specify the pressure range of the external steam source; when the pressure of the external steam source exceeds the specified range, the sterilizer shall alarm.

4.4.2.2 The manufacturer shall specify the external water source pressure range; when the external water source pressure exceeds the specified range, the sterilizer shall alarm.

4.4.2.3 The manufacturer shall specify the external compressed air pressure range; when the external compressed air pressure exceeds the specified range, the sterilizer shall alarm.

4.5 Data transmission Sterilizers used in laboratories or other places with a biosafety level of level 3 or 4 shall have data transmission systems and data transmission interfaces. Data can be transmitted through wired communication (such as Ethernet, fax, and audio and video monitoring) or wireless communication.

4.6 Drainage safety

4.6.1 The sterilizer shall be equipped with a sampling interface for condensed water discharged from the sterilization chamber.

4.6.2 The condensed water discharged from the sterilization chamber shall be sterile.

4.7 Exhaust safety

4.7.1 For sterilizers used in laboratories or other places with a biosafety level of level 2, it shall be determined whether the exhaust gas from the sterilization chamber uses a sterilization device based on the risk assessment results. If necessary, the exhaust gas from the sterilization chamber shall pass through at least a one-stage sterilization device, and the exhaust gas from the sterilization chamber shall be sterile.

4.7.2 For sterilizers used in laboratories or other places with a biosafety level of level 3, the exhaust gas from the sterilization chamber shall pass through at least a one-stage sterilization device, and the exhaust gas from the sterilization chamber shall be sterile.

4.7.3 For sterilizers used in laboratories or other places with a biosafety level of level 4, the exhaust gas from the sterilization chamber shall pass through at least a two-stage sterilization device, and the exhaust gas from the sterilization chamber shall be sterile.

4.7.4 If a high-efficiency filter is used as a sterilization device for the exhaust gas, the filter shall meet the following requirements:

a) The filtration efficiency of particles with a diameter of 0.2 μm shall not be less than 99.99%;

b) Be able to withstand high-temperature steam not less than 140 °C;

c) Use hydrophobic filter element;

5.2 Instrument and display device test

5.2.1 For sterilizers used in laboratories or other places with a biosafety level of level 3 or 4, refer to the quality certification documents of the pressure gauge and pressure sensor provided by the manufacturer to determine whether the diaphragm type is used.

5.2.2 Run the sterilizer program and check whether the display device in the non-containment area of the double-door sterilizer can display the cycle operation status.

5.3 Control system test Check whether the use authority of the control system is managed at level three or above.

5.4 Alarm test

5.4.1 Abnormal alarm test of exhaust gas filter Check whether the manufacturer has specified the range of pressure difference before and after the exhaust gas filter. Connect a manually adjustable valve in series at the pressure sensor in front of the exhaust gas filter; when the program runs to the state of decreasing pressure in the inner chamber, the process of adjusting the valve from open to closed causes the pressure difference between both ends of the filter to increase. Connect an adjustable valve in series at the pressure sensor at the rear of the exhaust gas filter; when the program runs to the state of decreasing pressure in the inner chamber, the process of adjusting the valve from open to closed causes the pressure difference between both ends of the filter to decrease. Simulate the pressure difference between the front and rear ends exceeding or falling below the set value, and check whether the sterilizer alarms.

5.4.2 Abnormal alarm test of external public facilities

5.4.2.1 Check whether the manufacturer has specified the pressure range of the external steam source; set the pressure of the external steam source to a value higher or lower than the specified pressure range and check whether the sterilizer alarms.

5.4.2.2 Check whether the manufacturer has specified the pressure range of the external