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Pharmaceutical equipment - General technical requirements for bioreactors

制药装备 生物反应器通用技术要求

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work

Guidelines Part

1.Structure and Drafting Rules of Standardization Documents". Drafting. Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents. This document was proposed and is under the jurisdiction of the National Technical Committee on Standardization of Pharmaceutical Equipment (SAC/TC356). This document was drafted by: Shandong Xinhua Medical Instrument Co., Ltd., Chengdu Yingde Biomedical Equipment Technology Co., Ltd., and Chutian Technology. Technology Co., Ltd., Dongfulong Technology Group Co., Ltd., Shanghai Gaoji Bioengineering Co., Ltd., Shandong Jiuzhe Heat Exchange System Co., Ltd. The company, Henan University, and Shandong Hongbang Centennial Bioengineering Co., Ltd. The main drafters of this document are. Zhu Qingguo, Li Chunyang, Yang Wenlu, Zheng Jinwang, Jin Kuiqi, Liu Hanqi, Zhang Rui, Wang Dong, Han Feifei, and Liu Zhi. Yao Jianlin, Liu Qiang, Han Qiang, Liu Yingtao, Zhao Hao, Liu Hui, Song Chuanbing, Zhang Yushan, Zhang Xianheng, Ding Hongyong, Sun Yang, Song Youxing. General Technical Requirements for Bioreactors in Pharmaceutical Equipment

1.Scope This document specifies the requirements, inspection rules, marking, packaging, transportation, and storage of bioreactors for pharmaceutical equipment, and describes the corresponding tests. method. This document applies to the design, manufacture, inspection, and testing of stainless steel stirred tank bioreactors (hereinafter referred to as "bioreactors") used in pharmaceutical equipment. Acceptance, etc.

4.1 Materials

4.1.1 All materials that come into direct contact with the materials or process media with specific requirements shall be non-toxic, corrosion-resistant, and non-shedding, and shall not come into direct contact with the materials or process media with specific requirements. The process medium undergoes a chemical reaction, adsorption, or releases substances into the material. Materials of components requiring sterilization or disinfection should be able to withstand high-temperature steam or... Sterilization and disinfection of chemical gases.

4.1.2 For all metallic materials that come into direct contact with the material or the required process medium, their quality certification documents should include, but are not limited to, material specifications. Specifications, material test reports (composition, mechanical/physical properties, etc.), manufacturing method/process documents, and certification documents for sanitary applications.

4.1.3 All polymers and other non-metallic materials that come into direct contact with the material or the required process medium should be able to fully guarantee the product or process. The purity, integrity, and potency of the fluid should be assessed, and the effects of time, temperature, etc., on material properties should be demonstrated. Quality certification documents should include, but are not limited to, these certifications. Regarding material

specifications, material test reports (composition, mechanical/physical properties, biocompatibility, etc.), manufacturing method/process documents, and those used for hygiene Supporting documentation for Class A operating conditions.

4.2 Surface Quality

4.2.1 The inner surface of the bioreactor should be smooth and flat, with no blind spots for cleaning.

4.2.2 All corners of metal surfaces in direct contact with materials should have smooth transitions; their surface roughness Ra value should not exceed 0.4 μm, and should... After acid pickling and passivation or electrolytic polishing.

4.3 Appearance

4.3.1 The control components of the control cabinet should be arranged reasonably, and the wiring should be horizontal and vertical without crossing; the instruments on the control cabinet panel should have clear labels. The outer surface should be easy to clean.

4.3.2 Pipelines and valves shall be arranged neatly, and the names of media and flow directions in the pipelines shall comply with the provisions of Chapter 8 of GB 2894-2025.

4.4 Containers and Piping

4.4.1 Bioreactors equipped with in-situ cleaning (CIP) functionality for the feed pipeline during production should have appropriate measures to prevent in-situ cleaning. Cleaning (CIP) liquid contamination culture system.

4.4.2 Fittings for removable inner tubes shall use aseptic union threaded connections.

4.4.3 Gravity discharge pipelines should have a continuous slope towards the discharge point, and the slope should not be less than 1%.

4.5 Pressure Vessels and Pressure Piping

4.5.1 The pressure vessel of the bioreactor shall comply with the relevant provisions of GB/T 150 (all parts), and the heat exchanger shall comply with GB/T 150 (parts). (Some of them) and the relevant provisions of GB/T 151.

4.5.2 The pressure piping of the bioreactor shall comply with the provisions of GB/T 20801 (all parts).

4.6 Stirring Components

4.6.1 The agitator and its components in the bioreactor shall not impede the discharge of materials from the container.

4.6.2 The agitator of the bioreactor should have a debris well or other structure to prevent particulate debris from entering the bioreactor.

4.7 Intake Components

4.7.1 Flow control devices (such as rotor flow meters, mass flow controllers, and regulating control valves) should be installed outside the sterilization filter, and should It has backflow protection measures to avoid damage to the instrument during in-situ sterilization (SIP) or gas recirculation.

4.7.2 For two-stage air intake filters used in series, the air intake filter assembly closest to the bioreactor should be a sterilizing filter.

4.7.3 The air inlet filter should be installed above the liquid level in the bioreactor.

4.8 Exhaust Assembly

4.8.1 For two-stage exhaust filters used in series, the exhaust filter assembly furthest from the bioreactor should be a sterilizing filter. There should be a device for draining condensate between the filters.

4.8.2 Condensate in the bioreactor exhaust assembly should not clog the exhaust filter.

4.8.3 The tank pressure control device should be installed outside the sterilization filter.

4.9 Performance

4.9.1 The rotation speed of the agitator in the bioreactor should be adjustable within the set range, and the control error should be within ±5% of the set value.

4.9.2 The bioreactor should be able to set and control the temperature within the range of 25°C to 40°C, and the control error should be within ±0.5°C of the set value. Within the enclosure.

4.9.3 The bioreactor should be able to set and control the pH within the range of 2 to 12, and the control error should be within ±

0.2 of the set value.

4.9.4 The bioreactor should be able to set and control dissolved oxygen (DO), and the control error should be within ±10% of the set value.

4.9.5 The sealing of the connecting pipes, valves and other components of the bioreactor should be free of abnormal noise and air leakage during pressure holding.

4.9.6 Bioreactors should be capable of cleaning in place (CIP) and sterilizing in place (SIP).

4.9.7 The components inside the bioreactor tank should not impede the self-discharge of materials by gravity discharge.