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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB 28670-2012

General rule of pharmaceutical machinery conforming to good manufacturing practice

制药机械（设备）实施药品生产质量管理规范的通则

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Foreword

Chapter 4 of this standard

4.4 are recommended, the rest are mandatory. This standard according to "Good Manufacturing Practice (revised 2010)," the relevant requirements and GB/T 1.1-2009 given rules Drafted. This standard is proposed and managed by the National Pharmaceutical Equipment Standardization Technical Committee (SAC/TC356). This standard drafting units. China Pharmaceutical Equipment Industry Association, Chongqing Branch Xu Pharmaceutical Machinery Equipment Manufacturing Co., Ltd., Chinese medicine Group Chongqing Medical Institute. Participated in the drafting of this standard. Shanghai Far East Pharmaceutical Machinery Co., Ltd., Shanghai Pharmaceutical Machinery Co., Ltd. Taiwan Intertek health. The main drafters. Zheng Guozhen, Wu Xia, Shi Qing, Sun Jinlian, high cloud-dimensional, real Chen Lu, Dong Chunliang. Pharmaceutical Machinery (apparatus) Embodiment Good Manufacturing Practices of General

1 Scope

GB 28670-2012 is the Chinese national standard on general rule of pharmaceutical machinery conforming to good manufacturing practice, in the field of health care technology. It carries no /T suffix, which in the Chinese system means compliance is mandatory: a product or a practice within its scope has to meet it to be lawfully made, sold or carried out in China. It was issued on 3 September 2012 by the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China; Standardization Administration of China, and has been in force since 1 July 2013. Classification: ICS 11.120, CCS C90. This page is published from the official record of the standard held by the Chinese standards administration: the identification, the dates, the classification and the issuing body are taken from there. The clause text, the tables and the numeric limits are in the document itself, which is delivered complete in English translation.

This standard specifies Pharmaceutical Machinery (equipment) with the general requirements of "Good Manufacturing Practice" of. It is also a pharmaceutical machinery (equipment) The basic requirements of product quality control and management. This standard applies to pharmaceutical machinery (equipment) in product design, manufacturing, testing, installation, operation, maintenance and verification.

2 Normative references

The following documents for the application of this document is essential. For dated references, only applies to the version dated paper Pieces. For undated references, the latest edition (including any amendments) applies to this document.

GB 150.1-2011 pressure vessel Part 1. General Requirements

GB 151-1999 shell and tube heat exchanger

GB 3836.1-2010 explosive atmospheres - Part 1. General requirements Device

GB/T 4272-2008 General equipment and piping insulation technology

GB 5226.1 Electrical safety of machinery Electrical machinery equipment Part 1. General requirements

GB 5959.6-2008 Safety Part heating means 6. safety regulations industrial microwave heating apparatus

GB/T 9969 General Industrial Product Manual

GB 12158-2006 General Guidelines to prevent static electricity accident

GB/T 15692-2008 pharmaceutical machinery term

GB 17914-1999 flammable and explosive goods storage and preservation

GB 17916-1999 toxic goods storage and preservation

GB/T 28671-2012 Pharmaceutical Machinery (equipment) Verification Guidelines

GB 50231-2009 mechanical equipment installation construction and acceptance of universal norms Toxic hazards and degree of chemical hazard classification HG20660-2000 media explosion pressure vessel TSGD0001-2009 Pressure Pipeline Safety Supervision Regulations (the State Administration of Quality Supervision, Inspection and Quarantine No. 44 of 2009 announcement) TSGR0004-2009 State Administration of Fixed Pressure Vessel Safety Technical Supervision Regulation (Quality Supervision, Inspection and Quarantine in 2009 Announcement No. 83) Good Manufacturing Practice (revised 2010) (People's Republic of China Ministry of Health Decree of

3 Terms and Definitions

GB/T 15692-2008 and defining the following terms and definitions apply to this document.

3.1 Dust dust It can be suspended in the air for a long time the suspended solids.

3.2 Isolator operator isolator It always refers to an internal environment from the external environment with Class B (ISO 5 level) or higher purity levels of the air cleaning device, and (e.g. It apparatus or system in a clean room and the operator) is completely isolated.

3.3 Intervention limited isolation barrier system (RABS) restrictedaccessbarriersystem Forming an isolation barrier between the drug and production operators, providing a "door" type operation or allows very little dielectric loading type Into its internal environment is a class A, the background environment of class B, aseptic unit interposed between the clean rooms and isolators.

3.4 Non-ionizing radiation non-ionizingradiation Wavelength > 100nm electromagnetic radiation sufficient to cause ionization of the organism. It comprises a high frequency electromagnetic field, microwave radiation, laser radiation, ultraviolet radiation Fire and so on.

4 General

4.1 General Requirements Pharmaceutical Machinery (equipment) in the design, manufacture, testing, installation, operation, maintenance and verification should meet pharmaceutical production processes and the corresponding "drug Health Requirements production quality management practices "(revised 2010), in line with the intended use. Should minimize contamination during pharmaceutical production, Cross-contamination, such as the risk of confusion and error. It should be easy operation, maintenance, disinfection or sterilization and for cleaning necessary.

4.2 Quality Management System Pharmaceutical Machinery (equipment) designs, manufactures organization shall establish a quality control system.

4.3 Training The organization shall carry out their duties and Pharmaceutical Machinery (equipment) design, production and personnel involved in quality management, standards, skills, etc. Training.

4.4 Product Quality Evaluation Product quality evaluation should be implemented, complete all the required inspection, testing, validation, parameter compliance, approved release.

4.5.1 Principles

4.5.1.1 Pharmaceutical Machinery (equipment) designed prior to manufacturing, the main material should confirm its primary function, technical performance parameters, and in contact with the medium Structure, cleaning and disinfection (sterilization) way, control and maneuverability, and its impact on drug production environment should be consistent with "drug Good Manufacturing Practice "(2010 revision), user needs and requirements of the corresponding product standards.

4.5.1.2 Pharmaceutical Machinery (equipment) should be energy saving, environmental protection, safe, reliable, and easy operation and maintenance, ease of cleaning, disinfection or sterilization.

4.5.1.3 Pharmaceutical Machinery (equipment) automatic control and intelligent monitoring levels should meet the needs of the development of pharmaceutical production. Use of electronic data Processing system Pharmaceutical Machinery (equipment) should be used in passwords or other means to control sign-on system, data input, change and delete data, and There are records.

4.5.2 The main material

4.5.2.1 Pharmaceutical Machinery material (equipment) or with drugs required process medium should be in direct contact with non-toxic, corrosion resistant, do not fall off, does not Drugs or process media required chemical reaction, adsorption, or release of the substance to the drug. Need disinfection and sterilization components material should High temperature steam or chemical sterilization gas.

4.5.2.2 Pharmaceutical Machinery (equipment) filter used should not shed fibers, asbestos, not react with the product, or the release of substances adsorbed substance. Insulating material particles must not fall off, not pollute the environment and drugs. Materials

4.5.2.3 pressure apparatus main pressure elements should meet the requirements and other mandatory GB 150-2011 standard.

4.5.3 Surface quality

4.5.3.1 Pharmaceutical Machinery (equipment) appearance surface (a surface including insulation) should be smooth, flat, no cleaning blind, without falling particles. Allowing the surface coating of the coated layer should be dense, must fall off.