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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

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Verify guidance for computerized system of pharmaceutical machinery (equipment)

制药机械（设备）计算机化系统验证指南

Issued on: March 17, 2023 **Implemented on: October 1, 2023**

Issued by: State Administration for Market Regulation;
Standardization Administration of China

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Foreword

This document is in accordance with the provisions of GB/T 1:1-2020 "Guidelines for Standardization Work Part 1: Structure and Drafting Rules for Standardization Documents" drafting: Please note that some contents of this document may refer to patents: The issuing agency of this document assumes no responsibility for identifying patents: This document is proposed and managed by the National Pharmaceutical Equipment Standardization Technical Committee (SAC/TC356): This document was drafted by: Shandong Xinhua Medical Devices Co:, Ltd:, Zhejiang University, Zhejiang Canaan Technology Co:, Ltd:, Truking Technology Co:, Ltd: The main drafters of this document: Zhang Qingjie, Cui Yuanfu, Liu Xuesong, Wu Wutong, Yang Wenlu, Li Yerui, Xie Zhongze, Tan Liang, Xi Guangyao, Chen Yong, Long Tao, Liu Zhi, Ji Kunpeng, Luo Xiang, Fang Huan, Huang Shaoqing, Ma Guanglei, Li Xinhua, Wang Xuyong, Wang Dong, Ding Hongyong, Pan Xuhui, Han Yao, Zhang Licun, Wang Hongmin: Guidelines for Validation of Computerized Systems for Pharmaceutical Machinery (Equipment)

1 Scope

This document gives guidance on validating the computerized systems built into pharmaceutical machinery: the lifecycle of the validation, the documents it produces, and what has to be demonstrated before the system is used in production. Every piece of pharmaceutical equipment is now a computer with a hopper attached, and the regulator treats the software as part of the machine. Validation is what turns a supplier's claim that the control system works into evidence an inspector will accept - and it is where a Chinese equipment purchase most often runs into trouble with a Western quality department. Issued on 17 March 2023 by SAMR and SAC as a guiding technical document, in force from 1 October 2023. It reads together with GB/Z 42540 on containment: one covers what the

machine keeps in, the other what its software has to prove.

This document provides guidelines for the verification of pharmaceutical machinery (equipment) computerized systems, including general principles, verification procedures, system verification schemes, Personnel training and validation document management: This document is applicable to the verification of pharmaceutical machinery (equipment) computerized systems, pharmaceutical manufacturers, pharmaceutical equipment manufacturers, third-party Certification agencies can refer to it:

2 Normative references

This document has no normative references:

3 Terms and Definitions

The following terms and definitions apply to this document: 3:

1 Production equipment that completes and assists in the completion of the pharmaceutical process: [Source: GB/T 15692-2008, 2:1] 3:

2 It is a system composed of a series of hardware and software to meet the specific functions of pharmaceutical machinery (equipment) in the quality management process of pharmaceutical production:

Note: Hereinafter referred to as the system: 3:3 validation report validationreport Documents for reviewing, reviewing and evaluating the verification scheme and the results of completed verification tests, missing items and deviations: [Source: GB/T 28671-2012, 3:9] 3:

4 Electronic signature electronic signatures Electronic data is the data contained in electronic form and attached to identify the signatory and to indicate that the signatory approves the content: 3:5 electronic data electronic data Information generated, sent, received or stored by electronic, optical, magnetic or similar means: 3:

6 The whole life cycle of the system lifecycleofsystem The process of a computerized system from the presentation of user requirements to its end of use:

Note: The full life cycle of the system includes design, standard setting, programming, testing, installation, operation, maintenance and other stages, hereinafter referred to as the life cycle: