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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

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**Technical guide for containment of pharmaceutical equipment -
Solid preparations**

制药装备密闭性技术指南 固体制剂

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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: Zhejiang Canaan Technology Co., Ltd., Tongji University, Sichuan Kelun Pharmaceutical Co., Ltd., Shandong Xinma Pharmaceutical Equipment Co., Ltd: The main drafters of this document: Fang Zheng, Xie Nan, Xie Zhongze, Wang Hongmin, Wu Guoqiao, Wu Wutong, Tan Hongbo, Dai Huafeng, Yu Jun, Yang Yulong, Wang Hui, Huang Yuanyuan, Cai Gen: Pharmaceutical Equipment Containment Technical Guidelines for Solid Preparations

1 Scope

This document gives technical guidance on containment in pharmaceutical equipment for solid dosage forms: how a machine that handles active powder is designed and operated so that the powder stays inside it. Containment is the discipline that decides whether an operator can be in the room. Modern active ingredients are potent at microgram exposure, and a tablet press or a granulator that leaks is not a housekeeping problem but an occupational one. The guidance covers the design features, the performance levels and the way containment is verified on the installed machine. Issued on 23 May 2023 by SAMR and SAC as a guiding technical document, in force from 1 December 2023. Directly relevant to anyone buying Chinese solid-dosage equipment or auditing a Chinese contract manufacturer.

This document provides the occupational exposure level and sealing technology application of solid preparation equipment with chemical hazard factors occupational exposure control

requirements: and assessment guidelines: This document is applicable to solid preparation equipment for the production and preparation of pharmaceuticals in a closed manner:

2 Normative references

The contents of the following documents constitute the essential provisions of this document through normative references in the text: Among them, dated references For documents, only the version corresponding to the date is applicable to this document; for undated reference documents, the latest version (including all amendments) is applicable to this document:

GB/T 36030 General Technical Requirements for Cleaning in Place and Sterilization of Pharmaceutical Machinery (Equipment)

GB 37823 Emission Standard of Air Pollutants for Pharmaceutical Industry EJ/T 1096-1999 Classification of airtightness of sealed chambers and its inspection methods

3 Terms and Definitions

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

1 The long-term repeated exposure of workers to one or more occupational harmful factors in the process of occupational activities will not cause discomfort to most of the exposed workers: Tolerable exposure levels for adverse health effects: [Source: GB /Z 2:1-2019, 3:5, modified] 3:

2 Chemical substances, dust and biological factors present or generated in the workplace: [Source: GB /Z 2:1-2019, 3:1, modified]

4 Abbreviations

The following abbreviations apply to this document:

5 Occupational Exposure Level (OEB) and the way to achieve it 5:

1 Confirmation of OEB and common engineering control measures Selecting a reasonable OEB grade according to the OEL values of different APIs facilitates the selection of suitable production facilities and operating procedures: