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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 46204-2025

Requirement for traceability management in medicinal product cold chain logistics

药品冷链物流追溯管理要求

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Table of Contents

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 Logistics Standardization Technical Committee (SAC/TC269). This document was drafted by: China Federation of Logistics and Purchasing, Jointown Pharmaceutical Group Logistics Co., Ltd., and the National Medical Products Administration. Information Center, Chengdu High-tech Industrial Development Zone Market Supervision Administration, Eli Lilly and Company Limited, Beijing Institute of Biological Products Co., Ltd. The company, Changzhou Institute of Pharmaceutical Research Co., Ltd., Beijing Sinovac Biotech Co., Ltd., Liaoning Chengda Biotechnology Co., Ltd., and North China Pharmaceutical Group Co., Ltd. Tanzania Biotechnology Co., Ltd., Changchun Jinsai Pharmaceutical Co., Ltd., Shanghai Pharmaceuticals Holding Co., Ltd., and Sinopharm Group Pharmaceutical Logistics Co., Ltd. Company, Guangzhou Pharmaceutical Co., Ltd., Hunan Pharmaceutical Group Co., Ltd., Qingdao Baiyang Pharmaceutical Co., Ltd., Shanxi Junlin Pharmaceutical Co., Ltd. Ren Company, Shandong Yiyang Health Group Pharmaceutical Co., Ltd., Shanghai Shengsheng Logistics Co., Ltd., Sinopharm Logistics Co., Ltd., Beijing Shengshihua Ren Supply Chain Management Co., Ltd., China Post Express & Logistics Co., Ltd., Beijing Yingji Pharmaceutical Cold Chain Technology Co., Ltd., Shanghai Tengyi Boshi Supply Chain Co., Ltd., Chengdu Yisu

Logistics Co., Ltd., Shanghai Baicheng Pharmaceutical Supply Chain Management Co., Ltd., Zhejiang Provincial Institute of Quality Science Research Institute, Chengdu Institute of Metrology and Testing, China United Health Medical Big Data Co., Ltd., Shanghai Siboyuan Cold Chain Technology Co., Ltd. Beijing Longbang Technology Development Co., Ltd., Beijing Yuwei Technology Co., Ltd., Jiangsu Jingchuang Electric Co., Ltd., Sichuan Wanwu Jinian Information Technology Co., Ltd. Information Technology Co., Ltd., Zhongsanqian Jinsheng (Beijing) Construction Co., Ltd., Zhejiang Weisong Cold Chain Technology Co., Ltd., Beijing Zhongke Hope Internet of Things Network Technology Co., Ltd., Hangzhou Nenggong Technology Co., Ltd. The main drafters of this document are. Qin Yuming, Zhang Qingsong, Lu Ying, Yang Jiao, Guo Wei, Xu Chao, Li Yanfeng, Geng Wenxin, Li Jing, Yang Junwei, and Zhang Weiting. Yang Liu, Wang Xiaoxiao, Li Bingnan, Ren Gang, Zhao Lidong, Liang Zhiyu, Chen Rongbo, Zhu Chengjun, Miao Feng, Sun Haitao, Liu Chaojun, Song Wenmei, Qin Jinna Yang Ming, Zhang Kaiyi, Ding Yanli, Zeng Xiaolan, Shao Ying, Wang Lijian, Yang Hongyan, Du Wei, Wang Zhongwei, Wang Chao, Wang Weikang, Li Xiaofan, Wang Yaping Ye Min, He Linghua, Wang Fangmin, Wang Bin, Miao Yongming, Xu Yalan, Liu Yang, Li Hao, Chang Yangyang. Requirements for Traceability Management of Pharmaceutical Cold Chain Logistics

1 Scope

GB/T 46204-2025 is the Chinese national standard covering following a temperature-controlled medicine through the chain - the identifiers at pack and pallet level, the temperature record tied to the consignment rather than to the vehicle, the handover events, and the excursion that has to be recorded and judged before the goods are released. First edition, already in force. Issued on 5 October 2025, it has been in force since 5 October 2025.

This document specifies the basic requirements, traceability content, information collection and recording, information management, and traceability procedures for pharmaceutical cold chain logistics. The content to be implemented. This document applies to the traceability of pharmaceutical cold chain logistics processes.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are not included. For references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies. This document.

GB/T 28842-2021 Standard Operation Specifications for Cold Chain Logistics of Pharmaceuticals

3 Terms and Definitions

The terms and definitions defined in GB/T 28842-2021, as well as the following terms and definitions, apply to this document.

3.1 traceability By monitoring, recording, and identifying, we can track and trace the history, application, or location of an object.

Note. Traceability includes tracking and tracing the source. [Source: GB/T 38155-2019, 2.2, with modifications]

3.2 Identifying The process of identifying and recognizing codes as symbols. [Source: GB/T 38155-2019, 3.11]

4 Basic Requirements

4.1 The pharmaceutical cold chain logistics service provider (hereinafter referred to as the "service provider") shall establish a traceability system, assign relevant personnel, and clearly define the traceability scope. Content and standardized traceability process.

4.2 Service providers shall be equipped with qualified temperature monitoring and recording equipment to monitor and record the temperature throughout the entire cold chain logistics process of pharmaceuticals. Warehousing service providers should also be equipped with humidity monitoring and recording equipment, and monitor and record humidity during the warehousing process.

Note. The equipment includes a temperature and humidity monitoring system and temperature and humidity measuring point terminals.

4.3 The service provider shall periodically verify the temperature and humidity monitoring system and calibrate or verify the temperature and humidity measuring terminal.

5 Traceable Content

5.1 Basic Information The traceability information for pharmaceutical cold chain logistics should include the basic information given in Table 1. Table

1 Basic Information Information type Information content Drug Information Generic name, Trade name, Manufacturer, Marketing Authorization Holder/Domestic Responsible Person, Batch Number, Expiry Date, Dosage Form, Specification Price, quantity, drug qualification certificate information, storage conditions, transportation conditions Client Information. Client's name, address, and contact information. Warehouse Information Basic information of the warehousing service provider (including name, address, and contact information), inbound time, temperature and humidity data during storage, and outbound time. In the meantime, the basic information of the party picking up the goods (including name, address, and contact information) should be provided. Transportation Information Shipper's

basic information (including name, address, and contact information), transportation service provider's basic information (including name, address, and contact information) Method), consignee's basic information (including name, address and contact information), means of transport information, departure time, departure temperature, and transportation process. Process temperature data, arrival time, arrival temperature Other abnormal information (including time, cause, and handling measures).

Note. Information on the traceability of narcotic drugs, psychotropic substances, and radioactive materials can be found in the "Regulations on the Administration of Narcotic Drugs and Psychotropic Substances," the "Measures for the Administration of the Operation of Narcotic Drugs and Psychotropic Substances (Trial)," and the "Radioactive Substances..." Regulations on Drug Administration, Regulations on the Administration of Toxic Drugs for Medical Use, and Regulations on the Administration of Anesthetic Drugs and Class I Psychotropic Drugs in Medical Institutions. a. Drug qualification certification information includes the "Drug Inspection Report", "Imported Drug Registration Certificate", "Drug Registration Certificate", "Drug Re-registration Approval Notice", and "Imported..." Drug Inspection Report, Origin Inspection Report, Customs Clearance Certificate, Batch Release Certificate for Biological Products, etc. For specific sources, please refer to the "Drug Administration Law of the People's Republic of China". The Law of the People's Republic of China on Drug Registration Management, the Law of the People's Republic of China on Import and Export Commodity Inspection, the Customs Law of the People's Republic of China, and the Law of the People's Republic of China on Batch Release Management of Biological Products Management Measures, etc.

5.2 Additional Information When requested by the client, the traceability information for pharmaceutical cold chain logistics should include the additional information given in Table 2. Table

2 Additional Information Information type Information content Client Information Unified Social Credit Code Warehouse Information Unified Social Credit Code of Warehousing Service Provider, Cargo Location Information, Codes of Temperature and Humidity Monitoring and Recording Equipment, Maintenance Records, In-Warehouse Inspection Check records. Inbound order number, Outbound order number Transportation Information Unified Social Credit Code of Transportation Service Provider, Unified Social Credit Code of Consignee, Code of Temperature Monitoring and Recording Equipment, Transportation Pre-delivery equipment inspection record, waybill number, delivery personnel information, and transportation tracking information. Other information related to facility and equipment verification report

5.3 Traceability Identification Traceability labels should be complete, clear, and identifiable.

6.1 Storage

6.1.1 Upon receipt of the goods, the service provider shall verify the drug information in