NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB 17405-2025

National food safety standard - Good manufacturing practice for healthcare products

食品安全国家标准 保健食品良好生产规范

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Foreword

This document was issued on 2 September 2025 by the State Administration for Market Regulation; Standardization Administration of the PRC and takes effect on 2 September 2026.

It is a GB standard without the /T suffix: compliance is mandatory in China.

1 Scope

GB 17405-2025 is the Chinese national food safety standard setting good manufacturing practice for health foods. Health foods sit between food and medicine in Chinese regulation - registered or filed with claimed functions, taken daily over long periods, and often by the elderly - so the manufacturing controls are pitched closer to pharmaceutical practice than to ordinary food processing, with validated processes and segregated work areas by product category. The standard sets the requirements for site selection and the factory environment, the buildings and workshops, the facilities and equipment, food safety management, the

raw materials, excipients and food-related products used, food safety control in production, validation, inspection, storage and transport, product recall and traceability, personnel training, and records and document management, with an annex giving guidance on dividing the work areas for the different categories of health food. It takes effect on 2 September 2026.

This Standard specifies the basic requirements and management guidelines for site selection and factory environment, factory buildings and workshops, facilities and equipment, food safety management, as well as raw materials, excipients and food-related products for health foods, food safety control in the production process, verification, inspection, storage and transportation, recall and traceability management, personnel training, record and document management, etc. of health food production enterprises.

This Standard applies to the production of health foods.

2 Terms and definitions

For the purpose of this Standard, the terms and definitions defined in GB 14881 and GB 16740 apply.

3 Site selection and factory environment

It shall comply with the relevant provisions of GB 14881.

4 Factory buildings and workshops

4.1 Basic requirements

It shall comply with the relevant provisions of GB 14881.

4.2 Design and layout

4.2.1 The work area shall be reasonably divided according to the product characteristics, production process, production characteristics, and cleanliness requirements in the production process of different dosage forms of health foods. Generally, it includes a clean work area and a general work area. Health foods in food form shall comply with the production area division requirements in the corresponding food production specifications.

4.2.2 Effective separation shall be provided between work areas with different cleanliness levels, and separate personnel and material flow passages shall be set up according to the cleanliness level to avoid cross-contamination. See Table A.1 in Annex A for an example of the clean work area division for non-food form health foods.

4.2.3 Clean work areas shall be equipped with independent air purification systems with filters and maintain positive pressure with adjacent non-clean work areas, to prevent unpurified air from entering and causing cross-contamination. Clean work area control requirements shall be implemented according to Table 1.

4.2.4 For production processes involving pre-processing steps such as raw material crushing, extraction, and purification, the work area for the raw material pre-processing steps shall be rationally designed according to product characteristics and production process requirements, effectively separated from the finished product production area, and separate personnel and material flow passages shall be set up.

4.2.5 Work areas with high dust generation shall have designs to prevent cross-contamination of dust, such as maintaining a relative negative pressure in the work area, using dust collection or removal facilities and equipment, and operating in a confined space.

5 Facilities and equipment

5.1 Basic requirements

It shall comply with the relevant provisions of GB 14881.

5.2 Facilities

5.2.1 At the entrance of the personnel flow passage in the clean operation area, facilities for changing clothes, changing shoes or shoe covers, hand washing, hand drying, and disinfection shall be reasonably provided. Necessary buffer and cleaning facilities shall be provided in the material flow passage.

5.2.2 If there are special requirements for water used in contact with food or requiring the use of purified water, corresponding preparation facilities shall be available, meeting the production process requirements and production needs.

5.2.3 Dehumidification, ventilation, and temperature control facilities that meet the requirements shall be provided according to the production process requirements.

5.3 Equipment

5.3.1 For production processes involving pre-treatment steps such as raw material crushing, extraction, and purification, production equipment suitable for raw material pre-treatment shall be provided. If the solvent used in extraction needs to be recovered, appropriate solvent recovery equipment that meets relevant requirements shall be provided.

5.3.2 The filling, packing, and sealing processes of the product shall be completed using automated equipment. For products where automation is truly impossible due to the special nature of the process, process validation shall be conducted to ensure that the product meets the quality and safety requirements and production process requirements for health foods.

5.3.3 Liquid health foods such as oral liquids (excluding products whose main raw materials and excipients are propolis and honey), liquid milk products, and beverages, as well as equipment and pipelines in direct contact with the product during raw material extraction or purification processes, shall be equipped with cleaning systems. Clean-in-place (CIP) is recommended for major equipment and pipelines. If clean-in-place (CIP) cannot be used and other cleaning methods are used, cleaning validation shall be conducted to ensure that the equipment's cleaning effect meets quality and safety requirements.

6 Food safety management

6.1 It shall comply with the relevant provisions of GB 14881.

6.2 A food safety control system shall be established and effectively operated in accordance with the principles of hazard analysis and critical control points.

6.3 A supplier management system shall be established, specifying the procedures for supplier selection, review, and evaluation. The process flow and food safety control measures adopted by suppliers shall be evaluated according to the evaluation