# GB

NATIONAL STANDARD OF THE

PEOPLE'S REPUBLIC OF CHINA

# GB 17405-1998

## Good manufacture practice for health food

保健食品良好生产规范

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# Good manufacture practice for health food

## 1 Scope

This standard stipulates the basic technical requirements for personnel, design and facilities, raw materials, production processes, storage and transportation of finished products, quality and hygienic management of food enterprises with specific health functions.

This standard applies to all health food production enterprises.

## 2 Normative references

The provisions in following documents become the provisions of this Standard through reference in this Standard. At the time of publication, the editions indicated were valid. All standards will be revised, all parties who use this Standard are encouraged to study if the latest versions of these documents are applicable.

GBJ 73-84 Design code for clean workshop

GB 5749-85 Sanitary standard for drinking water

GB 7718-94 General standard for the labelling of foods

GB 14881-94 Limited concentrations of radioactive materials in foods

## 3 Definition

This standard uses the following definition.

### 3.1 Raw materials

All inputs used in the production of health food, including processing aids and food additives.

### 3.2 Intermediate products

Substances or mixtures that require further processing.

### 3.3 Product

**5.2.6** The temperature and relative humidity of the clean workshop shall be compatible with the production process requirements.

**5.2.7** Sewers, hand washing and other sanitary cleaning facilities installed in clean workshops shall not cause pollution to the production of health food.

**5.2.8** There shall be buffer facilities between the workshops with different cleanliness levels and between the workshop and the passage. It shall provide personnel and material channels suitable for the cleanliness level separately.

**5.2.9** The pretreatment of raw materials (such as extraction, concentration, etc.) shall be carried out in a place suitable for its production scale and process requirements, meanwhile it is equipped with the necessary ventilation, dust removal, cooling facilities. The pretreatment of raw materials shall not use the same production workshop as the production of finished products.

**5.2.10** The production of health food shall have a preparation room. The cleanliness level of the preparation room shall be consistent with the requirements for production process.

**5.2.11** The air purification facilities and equipment of the clean workshop shall be regularly overhauled, during which it shall take appropriate measures so as not to cause pollution to the production of health food.

**5.2.12** Production of fermented products shall have a dedicated fermentation workshop and special equipment corresponding to fermentation and spraying.

**5.2.13** All production tools and equipment that are in direct contact with raw materials and intermediate products shall use materials that meet product quality and hygiene requirements.

## 6 Raw materials

**6.1** The purchase, use, etc. of raw materials required for the production of health foods shall be formulated with the system of acceptance, storage, use, inspection, etc., which shall be responsible by a dedicated person.

**6.2** The raw materials must meet the food hygiene requirements. The variety, source, specifications, quality of raw materials shall be consistent with the approved formula and product enterprise standards.

**6.3** Purchasing raw materials must obtain a valid inspection report in accordance with the relevant requirements; raw materials belonging to new food resources must obtain an approval certificate (copy) from the Ministry of Health.

degradation of the strain, or mutation-produced poison.

# 7 Production process

**7.1** Formulate production operation procedures

**7.1.1** The factory shall formulate production process regulations and post operation regulations in accordance with the requirements of this practice and the production process characteristics of its own products.

The production process procedures shall meet the technological requirements of no loss, destruction, conversion and no harmful intermediates of the effective ingredients during the processing of health food. The content shall include the product formula, the preparation of each component, the main technical conditions of the finished product processing, the quality and hygiene monitoring points of key processes, such as: temperature, pressure, time, pH value, quality index of intermediate products during the processing of finished products.

Post operation procedures shall specify specific operational requirements for each main production process, to clarify the job responsibilities of each workshop, process and individual.

**7.1.2** The production technology and management personnel of each production workshop shall record each batch of products from raw material preparation, intermediate product's output, product quality and hygiene indicators in accordance with the key process control items and inspection requirements in the production process.

**7.2** Collection and feeding of raw materials

**7.2.1** The raw materials must be strictly inspected before being put into production, to check the product name, specification, quantity. In case of the mold, insect growth, inclusion of foreign objects, other abnormal sensory traits, failure to meet the requirements of quality standards, it shall not be put into production. All raw materials that have a storage period shall not be used after they expire. Liquid raw and auxiliary materials shall be filtered to remove foreign materials; solid raw and auxiliary materials that need to be crushed and sieved shall be crushed to the specified fineness.

**7.2.2** The workshop collects the raw and auxiliary materials according to the production needs; calculates, weighs and feeds the materials correctly according to the formula. The calculation, weighing and feeding of the formula raw materials must be reviewed by two people and recorded for future reference.

**7.2.3** The quality of the production water must comply with the provisions of GB

solid products such as capsules, tablets, granules that need to be dried, it shall strictly control the temperature and time of the drying chamber (box), to prevent the particles from melting and deteriorating; the materials for crushing, tableting, sieving or granulating shall meet the hygienic requirements; it shall be regularly washed and maintained, to avoid contamination by rust and metal contaminants.

**7.3.7** Product tableting, capsule dispensing, granules, filling of liquid products, etc. shall be carried out in a clean room. The temperature and humidity of the operating room shall be controlled. Manual dispensing of capsules shall be carried out in a plexiglass cover with a corresponding clean level; the operating table shall not be lower than 0.7 m.

**7.3.8** The prepared materials must be placed in a clean airtight container and promptly entered into the procedures of filling, tableting or capsule dispensing, etc. Those needing storage shall not exceed the prescribed period.

**7.4** Washing, sterilization and cleaning of packaging containers

**7.4.1** It shall use the food containers, packaging materials, detergents, disinfectants that are allowed to be used in accordance with the hygiene standards and hygiene management methods.

**7.4.2** The raw materials such as empty capsules and sugar coatings must meet the hygienic requirements. It is prohibited to use the nonedible pigments.

**7.4.3** Various glass bottles (tubes), plastic bottles (tubes), bottle caps, bottle pads, stoppers, aluminum-plastic packaging materials, etc. for product packaging, if in direct contact to the internal packaging materials of the product, shall be cleaned, dried, sterilized by appropriate methods. After sterilization, it shall be placed in a clean room to cool it to prepare for use. If the storage time exceeds the prescribed period, it shall be washed and sterilized again.

**7.5** Product sterilization

**7.5.1** The sterilization of various products shall use effective sterilization or sterilization equipment and methods. For products that need to be sterilized and cannot be autoclaved, it may, according to different processes and food hygiene requirements, use such methods as fine filtration, microwave, irradiation, to ensure the sterilization effect. When the irradiation sterilization method is adopted, it shall strictly follow the provisions of the "Administrative measures on the sanitation of irradiated food" to control the absorbed dose and time of irradiation.

**7.5.2** The temperature uniformity and repeatability of the sterilization or sterilization device shall be regularly verified for reliability; the temperature, pressure and other testing instruments shall be regularly verified. In the

packaging.

**7.7.4** The maximum pressure (weight) shall be indicated on the product's outer packaging.

**7.8** Marking

**7.8.1** The product's marking must meet the requirements of "Provisions on identifying health food" and GB 7718.

**7.8.2** The printing of health food product instructions and labels shall be consistent with those approved by the Ministry of Health.

## 8 Storage and transport of finished products

**8.1** The general hygienic requirements for storage and transport shall meet the requirements of GB 14881.

**8.2** The storage method and environment of the finished product shall be protected from light and rain; the temperature and humidity shall be controlled within an appropriate range; it shall avoid impact and vibration.

**8.3** Products containing biologically active substances shall adopt corresponding cold storage measures and be stored and transported in a cold chain.

**8.4** Health foods (such as certain micro-ecological health foods) stored under other temperature than normal temperature shall be stored and transported at the required temperature according to different characteristics of the products.

**8.5** The warehouse shall have a warehousing-in/out inspection system. Finished products shall be delivered in accordance with the principle of "first production first sale".

**8.6** The warehousing-in of finished products shall have inventory records; the warehousing-out of finished products shall have delivery records, at least including the batch number, delivery time, location, object, quantity, etc., so as to recover them once finding problems.

## 9 Quality management

**9.1** The factory must set up an independent quality management organization that is compatible with the production capacity, directly under the leadership of the factory person in charge. There are full-time quality supervisors in each workshop, and part-time quality inspectors in each team to form a complete and

**9.5.1** Identify key quality and hygiene control points during processing, at least monitoring the following links and making records.

**9.5.1.1** Name and weight (or volume) of feeding materials.

**9.5.1.2** Temperature, pressure, time, pH and other technical parameters in the extraction process of active ingredients.

**9.5.1.3** Output rate and quality specifications of intermediate products.

**9.5.1.4** Output rate and quality specifications of finished products.

**9.5.1.5** The hygienic condition of the inner packaging materials in direct contact with food.

**9.5.1.6** Technical parameters of sterilization method of finished product.

**9.5.2** Important production equipment and measuring instruments shall be regularly overhauled. Thermometers and pressure gauges used for sterilization equipment shall be overhauled at least once every six months; meanwhile maintenance records shall be made.

**9.5.3** It shall have the ability to monitor the production environment; regularly monitor the temperature, humidity, air purification degree and other indicators of the key process environment.

**9.5.4** It shall have the ability to monitor production water and regularly monitor it.

**9.5.5** For abnormal conditions found in the quality management process, it shall quickly find the reasons and make records and corrections.

**9.6** Quality management of finished products

**9.6.1** The sensory, sanitary and quality indicators of the finished product must be inspected batch by batch. Those unqualified shall not be exit-factory.

**9.6.2** It shall have the ability to detect the main efficacy factors or efficacy components of the product; perform the testing according to the efficacy factors or major efficacy components of the product produced by each feeding. Those unqualified shall not be exit-factory.

**9.6.3** Each batch of products shall have a reserve sample, which shall be stored in a special reserve sample warehouse (or area), classified according to variety and batch number, have obvious signs.

**9.6.4** Product stability experiments shall be conducted regularly.

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