GB

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National Food Safety Standard -- Good Manufacturing Practice for Formulas for Special Medical Purposes

食品安全国家标准　特殊医学用途配方食品良好生产规范

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National Food Safety Standard -- Good Manufacturing Practice for Formulas for Special Medical Purposes

1 Scope

This Standard specifies the basic requirements and management guidelines for sites, facilities, and personnel in the production process of formula foods for special medical purposes such as raw material procurement, processing, packaging, storage, and transportation.

This Standard applies to the production of formula foods for special medical purposes.

2 Terms and definitions

For the purposes of this document, the terms and definitions defined in GB 14881, GB 25596 and GB 29922 apply.

3 Site selection and factory environment

They shall comply with the relevant provisions of GB 14881.

4 Factory buildings and workshops

4.1 Basic requirements

They shall comply with the relevant provisions of GB 14881.

4.2 Design and layout

4.2.1 Factories and workshops shall be reasonably designed, planned and constructed to be compatible with facilities and equipment to prevent microbial contamination and growth, especially contamination by pathogenic bacteria such as Salmonella. For infant formulas for special medical purposes, contamination by Cronobacter spp. (Enterobacter sakazakii) shall also be prevented. The following shall be considered in the design:

a) Wet and dry areas shall be effectively separated. Cross-contamination caused by the flow of personnel, equipment, facilities and materials shall be effectively controlled;

b) Properly plan the stacking of materials. Avoid places that are not conducive to cleaning due to improper stacking;

c) Enclose or seal various pipes, cables and penetration gaps that pass through building floors, ceilings and walls;

d) Wet cleaning processes shall be designed properly. Improper wet cleaning shall be prevented in dry areas;

e) The cleaning work area shall prevent the generation of condensation water.

4.2.2 Operations in dry processing areas without subsequent sterilization (or disinfection) operations, such as operations from drying (or post-drying) processes to filling and sealing packaging, shall be conducted in clean operating areas.

4.2.3 Products with subsequent sterilization (or disinfection) processes are in contact with ambient air before sterilization (or disinfection) (such as weighing, batching, etc.), and wet processing areas for powdered products (such as weighing, batching, concentration, etc.) can be performed in a quasi-clean work area. However, its safety shall be verified in accordance with the requirements of 9.2 and 9.4 to ensure the quality and safety of the product.

4.2.4 Effective separation shall be set up between working areas with different cleanliness levels. An independent air purification system with filtration device shall be installed in the cleaning work area. Maintain positive pressure. Prevent unpurified air from entering the clean work area and causing cross-contamination.

4.2.5 The cleaning work area shall be kept dry. Water supply facilities and systems shall avoid passing through the upper space of the main production operation surface. If it cannot be avoided, protective measures shall be taken to prevent contamination.

4.2.6 There shall be reasonable and effective control measures in and out of the cleaning work area to avoid or reduce microbial and other contamination. People, raw materials, packaging materials, waste, equipment, etc. who enter and leave the cleaning operation area shall take measures to prevent cross-contamination, such as setting up locker rooms for personnel to change work clothes, work shoes or shoe covers; materials entering the cleaning operation area must be removed from the outer packaging or the outer packaging shall be cleaned and disinfected; there are dedicated logistics channels and waste channels or waste sealing protection. If waste sealing protection is used, ensure that the sealing protection is intact. For materials transported through pipelines using airflow as a carrier to enter the cleaning operation area, an appropriate air filtration system shall be designed and installed for the carrier airflow.

4.2.7 The environment of the cleaning work area shall comply with the requirements in Table 1. For the production of infant formula for special medical purposes, the clean working area environment shall also comply with the requirements of GB 23790. The number of sedimentation bacteria in the air in the quasi-clean operation area shall be

5 Facilities and equipment

5.1 Facilities

5.1.1 Basic requirements

They shall comply with the relevant provisions of GB 14881.

5.1.2 Drainage facilities

5.1.2.1 Drainage facilities shall be avoided in clean work areas where solid products are produced. If installation is indeed necessary, appropriate measures shall be taken to keep the drainage facilities in a dry state during production.

5.1.2.2 Drainage systems shall have slopes. Keep them clear and easy to clean. There shall be no dead corners for cleaning at the joints between the sides and bottom of the drainage ditch, or corresponding measures shall be taken to prevent the accumulation of water. Drainage facilities in the work area shall prevent sewer backflow and turbid gas escape. Hygienic clean floor drains shall be used when necessary.

5.1.2.3 There shall be no water supply lines for process water in or below the drainage system.

5.1.3 Personal hygiene facilities

5.1.3.1 Changing rooms (including changing shoes or wearing shoe covers), hand washing and drying facilities, and disinfection facilities shall be set up near the entrance of the production site or production workshop.

5.1.3.2 Personnel shall take necessary cleaning measures before entering the cleaning work area. A dedicated locker room shall be set up at the personnel entrance. Set up hand disinfection facilities before entering the cleaning work area. Hand washing facilities are not required.

5.1.4 Ventilation facilities

5.1.4.1 Air conditioning facilities shall be installed in the cleaning work area. The power of air conditioning facilities shall meet the control requirements of workshop cleanliness, temperature, and humidity. In areas where odor, dust, steam or other harmful gases are generated, there shall be corresponding elimination, collection or control devices.

5.1.4.2 The outdoor air inlet shall be more than 2 m away from the ground or roof, and away from pollution sources and exhaust outlets. and equipped with air filtration device.

5.1.4.3 Compressed air or other gases used for food production and cleaning food contact surfaces and equipment shall be de-oiled, water removed, clean filtered and

sterilized before use.

5.1.5 Warehousing facilities

Refrigerated (frozen) warehouses shall be equipped with monitoring facilities such as thermometers, temperature measuring devices or automatic temperature recorders to monitor and record the temperature.

5.2 Equipment

5.2.1 Basic requirements

They shall comply with the relevant provisions of GB 14881.

5.2.2 Other requirements

5.2.2.1 Storage, transportation and processing systems (including gravity, pneumatic, closed and automatic systems, etc.) shall be easy to maintain in good sanitary condition.

5.2.2.2 Equipment spare parts shall be stored in dedicated areas. Keep spare parts storage areas clean and dry.

5.2.2.3 Equipment shall be verified or confirmed to ensure that various performances meet process requirements. In particular, equipment used for dry mixing shall be able to ensure that the product is mixed evenly. Measuring instruments and key instruments used in production shall be calibrated regularly. Production equipment shall have obvious operating state signs and shall be repaired, maintained and verified regularly. Equipment installation, repair, and maintenance operations shall not affect product quality.

5.2.2.4 Key equipment such as sterilization and mixing shall have operating state monitoring and fault alarm functions or effective monitoring measures.

5.2.2.5 When a computer system and its network technology are used for critical control point monitoring data collection and record management, the relevant functions of the computer system and its network technology may refer to the provisions of Annex A.

6 Health management

6.1 Basic requirements

They shall comply with the relevant provisions of GB 14881.

6.2 Factory and facility hygiene management

6.2.1 Regular inspections shall be carried out on the ceiling, walls, floors, equipment and facility connections and other locations in the cleaning work area. Discover and

6.4.2 Personnel shall undergo procedures such as changing clothes and disinfecting hands in the cleaning area before entering the cleaning area to ensure the hygiene of the hands of relevant personnel.

6.5 Waste disposal

Containers containing waste, processing by-products, and inedible or hazardous materials shall be specially labeled, properly constructed, and watertight. Containers shall be closed when necessary to prevent contamination of food.

7 Food raw materials, food additives and food-related products

7.1 Basic requirements

7.1.1 They shall comply with the relevant provisions of GB 14881.

7.1.2 A supplier management system shall be established to stipulate the procedures for supplier selection, review, and evaluation.

7.1.3 The raw materials, processes and food safety control measures used by suppliers shall be evaluated. Regular on-site reviews or monitoring of the production process shall be carried out when necessary.

7.1.4 The acceptance criteria for relevant raw materials and packaging materials shall be determined based on the characteristics of the product formula. Ensure product quality and safety needs are met.

7.2 Storage requirements

7.2.1 During storage, it shall be stored in zones according to the characteristics of different raw materials and packaging materials. Establish a logo to indicate relevant information and quality state.

7.2.2 Food additives shall be stored in a special warehouse or area. Use a special register (or warehouse management software) to record the name, purchase time, purchase volume and usage of food additives, etc. Pay attention to validity period.

7.2.3 The raw materials of products with special requirements for allergenic substances shall be separated or stored in special areas from the raw materials containing the specific allergenic substances. They shall be clearly marked to avoid access errors and contamination.

7.2.4 For raw materials such as vitamins whose quality is prone to change during storage, as well as raw materials and packaging materials whose quality may change due to storage conditions and other reasons, the quality shall be confirmed before use. Carry out sampling testing when necessary to ensure compliance with specified

requirements.

8 Food safety control during production

8.1 Basic requirements

8.1.1 They shall comply with the relevant provisions of GB 14881.

8.1.2 The relevant principles of hazard analysis and critical control points shall be followed. Establish and effectively operate a strict food safety control system.

8.1.3 Before each production, check whether the equipment is in normal condition.

8.1.4 When weighing and batching, ensure that the type and quantity of raw materials meet the requirements of the product formula. Weighing shall be accurate and have a review process. The types of raw materials shall be reviewed again when feeding. If a computer information system is used to realize automated control, manual review does not need to be used, but the computer information system shall have error-proofing design and regular verification.

8.2 Control of microbial contamination

8.2.1 Necessary measures shall be taken to prevent microbial contamination during the entire process from the entry of raw materials and packaging materials to the delivery of finished products.

8.2.2 Real-time temperature and humidity monitoring measures shall be established to control and record the temperature and humidity in the cleaning operation area. Verify regularly.

8.2.3 Methods to kill microorganisms or inhibit the growth and reproduction of microorganisms shall be adopted based on the characteristics of the product, such as heat treatment, freezing or refrigerated storage, etc. Establish temperature and time control measures and corrective measures. Implement effective monitoring and regular verification.

8.2.4 For processing links that strictly control temperature and time, real-time monitoring measures shall be established. Keep monitoring records.

8.2.5 Microbial monitoring

8.2.5.1 A microbial monitoring plan shall be developed for the production process with reference to Annex A in GB 14881-2013, combined with the requirements of the production process and relevant product standards such as GB 29922 and GB 25596. Implement effective monitoring. The total number of bacteria and Enterobacteriaceae are used as indicator bacteria. When monitoring results indicate deviations, appropriate

8.5.3 Key process parameters such as heat treatment time and temperature shall be recorded.

8.6 Intermediate product storage

8.6.1 Semi-finished products or containers shall be identified or recorded. Information such as name, production time, etc. can be obtained through identification or records.

8.6.2 According to the storage characteristics of the product, the storage temperature and time of the liquid intermediate shall be controlled to prevent the growth of microorganisms.

8.6.3 If exposed semi-finished products need to be temporarily stored in the production of solid products, they shall be stored in a clean working area. If they need to be placed outside the cleaning work area, measures such as sealed packaging shall be taken to prevent contamination. There shall be identification information such as name, production time, storage period and storage conditions.

8.7 Commercial aseptic processing of liquid products

The operating instructions in Anex C shall be used.

8.8 Control requirements for specific processing techniques of solid products

8.8.1 Drying of powdered products

During the production of powdered products, the transportation pipelines and equipment from heat treatment to drying shall be kept closed. Clean and disinfect material contact surfaces regularly.

8.8.2 Cooling

8.8.2.1 If the dried exposed semi-finished product needs to be cooled, it shall be done in a clean working area.

8.8.2.2 In the wet and dry-wet composite production of powdered products, monitoring measures shall be established for the air inlet temperature of the fluidized bed and the temperature of the semi-finished product at the outlet of the fluidized bed.

8.8.3 Dry mixing of powdery product dry process and dry-wet composite process

8.8.3.1 Bare powder processes that are in contact with ambient air (such as premixing and packaging, batching, and feeding) shall be carried out in a clean operating area.

8.8.3.2 The temperature and relative humidity of the cleaning operation area shall be monitored in accordance with the requirements in Table 1.

8.8.3.3 Key process parameters related to mixing uniformity (such as mixing time, etc.) shall be verified. The homogeneity of the mix shall be confirmed.

8.8.3.4 Strict hygiene control requirements shall be established for raw materials, packaging materials and personnel. Raw materials shall enter the work area through necessary cleaning procedures and material channels. The procedures for removing the outer packaging, or cleaning and disinfecting the outer packaging shall be followed.

8.8.4 Inner packaging

8.8.4.1 The inner packaging process shall be carried out in the clean operating area.

8.8.4.2 Raw materials and packaging materials and personnel entering the inner packaging room shall comply with the provisions of 8.8.3.4 and 6.4.

8.8.4.3 For powdery products, effective foreign matter control measures shall be adopted, such as setting up screens, strong magnets, and metal detectors; and effectiveness verification shall be implemented.

9 Verification

9.1 The production process needs to be verified to ensure the reproducibility of the entire process and the controllability of product safety. Verification shall include plant, facility and equipment installation verification, operation verification, performance verification and product verification.

9.2 Verification items shall be proposed based on the verification objects, verification plans shall be formulated, and implementation shall be organized.

9.3 The production process and key facilities and equipment of the product shall be verified according to the verification plan. When the main factors affecting product safety and quality (including nutritional ingredients), such as processes, safety and quality control methods, main raw materials and auxiliary materials, main production equipment, etc., change, and after a certain production cycle, re-verification shall be carried out.

9.4 After the verification work is completed, a verification report shall be formed, which shall be reviewed and approved by the person in charge of the verification work. The data and analysis content during the verification process shall be archived and saved in the form of files. Verification documents shall include verification plans, verification reports, evaluations and suggestions, approvers, etc.

10 Inspection

It shall comply with the relevant provisions of GB 14881.

Annex A

Computer system application guide for special medical purpose formula food manufacturing enterprises

A.1 The computer systems of enterprises producing formula foods for special medical purposes shall be able to meet the food safety regulatory requirements of the "Food Safety Law of the People's Republic of China" and its related laws, regulations and standards. A complete information chain shall be formed that helps trace, track, and locate food safety issues in every link from raw materials entering the factory to product leaving the factory. It shall be able to submit or remotely submit relevant data as required by regulatory authorities. The computer system shall meet (but not be limited to) the requirements of A.2~A.11.

A.2 The system shall include data collection and record keeping functions related to food safety in various aspects such as raw material procurement and acceptance, raw material storage and use, monitoring of key control links in production and processing, product exit-factory inspection, product storage and transportation, and sales.

A.3 The system shall be able to assess and provide early warning on the food safety risks of the company's relevant raw materials, processing techniques and products.

A.4 The system and supporting database shall establish and use a complete authority management mechanism. Ensure the mandatory use of staff accounts/passwords. In terms of security architecture, ensure that there are no loopholes in the system and database that allow unauthorized access.

A.5 On the basis of the authority management mechanism, the system shall implement a complete security policy. Set corresponding policy groups for different staff to ensure that users in specific roles only have corresponding permissions. All data contacted and generated by the system shall be stored in the corresponding database. They shall not be stored in file form. Make sure all data access is subject to system and database permission management controls.

A.6 Adopt special security policies for confidential information to ensure that only the owner of the information has the right to read, write and delete operations. If confidential information really needs to be stored and transmitted outside the security control scope of systems and databases, ensure that:

a) Encrypt and store confidential information to prevent unauthorized persons from reading the information;

b) A check code is generated before the confidential information is transmitted. The check code and the information (after encryption) are transmitted separately. The

check code is used at the receiving end to confirm that the information has not been tampered with.

A.7 If the system needs to collect data generated by automated detection instruments, the system shall provide a safe and reliable data interface. Ensure accuracy and high availability of interface parts. Ensure that the data generated by the instrument can be collected by the system in a timely and accurate manner.

A.8 Complete and detailed system and database log management functions shall be implemented, including:

a) System logs record every user login to the system and database (user, time, login computer address, etc.);

b) The operation log records every modification of data (including modification user, modification time, modified content, original content, etc.);

c) System logs and operation logs shall have storage strategies. Within the set time limit, no user (excluding system administrators) can delete or modify it to ensure traceability within a certain time limit.

A.9 Develop a system usage and management system, which must include at least the following:

a) A real-time recording system for original data, intermediate data, generated data and processing procedures in the work process to ensure that the entire work process can be reproduced;

b) A detailed backup management system ensures that the entire system and corresponding data can be fully restored as soon as possible after a disaster occurs;

c) The computer room shall be equipped with a smart UPS uninterruptible power supply and connected to the working system. Ensure that the UPS takes over the power supply in the event of an external power outage and notifies the working system to perform data saving and log operations (the UPS shall be able to provide power to ensure the system's emergency save operation time);

d) There is a sound data access management system, and confidential data is strictly prohibited from being stored on shared devices. Data sharing within departments shall also adopt a rights management system to achieve authorized access;

e) A supporting system maintenance system, including regular storage and system testing, ensures long-term stable operation of the system;

f) The security management system requires regularly changing the passwords of users in various parts of the system, limiting the login locations of some users, and promptly deleting accounts that are no longer needed;

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