

Guidelines for Good Agricultural Practice (GAP) of Medicinal Plants and Animals

I . General Part

1. The GAP Guidelines are formulated to standardize the production of Chinese medicinal materials, guarantee the quality of such materials, and promote the standardization and modernization of Chinese Materia Medica.
2. The GAP Guidelines serve as the basic principles for the production and quality management of medicinal and these guidelines are applicable to the whole production process, transportation and all major quality-managing procedures of Chinese medicinal materials (including medicinal plants and animals).
3. Standardized management and quality control policies should be adopted to regulate and control the exploitation raw materials in order to achieve "maximum sustainable yield", protecting Chinese medicinal resources towards a sustainable utilization.

II . Ecological Environment of Production Site

4. The production base should be established on sites selected according to its suitability for the medicinal Plants and Animals, determined by the ecological surroundings.
5. The production base enterprise should be established on a site that is free of air, water, and soil pollution. It should also be away from sources of pollution. The ecological conditions of the site should meet the following standards: air quality should be of "atmospheric conditions" standard, GB3095-82 Grade2; irrigation water quality should be of "farm irrigation" GB5084-92 Grade2; soil quality should be of GB15618-1995 Grade2; drinking water for medicinal animals should be of "daily drinking water" standard, GB5749-85.
6. Animal raising bases should not only fulfill the ecological requirements of the animal species, but also be equipped with appropriate constructions for their inhabitation and reproduction.

III. Seeds and Propagation Materials

7. Seeds, spores and propagation materials (all referred to as "seeds" blow) should be carefully identified botanically and zoologically, specifying their species, varieties, cultivars and origins. Animal spawns or broods should, confirming to the above standards, be specified according to their species, subspecies, varieties and origins.
8. In order to ensure the quality of seeds and prevent the spread of pests and weeds, proper inspection and quarantine procedures of the seeds should be implemented in time of seed production, storage and transportation. Storage time and method for different types of plant seeds should be stipulated according to their respective properties, In such a way, the mixing and interspersing of poor quality seeds among the good ones could be prevented.
9. The introduction and domestication of animal breeds should be based on extensive investigation and profound understanding of their properties. Physical of mental injuries to the animals should

be avoided when capturing and transporting the animals. Imported breeds should be strictly inspected and should be quarantined for observation over a period of time.

10. A propagation base for high quality species should be established. It should be served as a center for organizing the supply of high quality propagating materials. A regionalized distribution of species and specialization in seeds (broods) production, mechanization in processing and standardization in quality should be gradually achieved in the propagation base.

IV. Cultivation and Raising Management

A. Cultivation Management of Medicinal Plants

11. Standard Operating Procedures of cultivation should be formulated according to the different growing and development needs of plant species.
12. The application of fertilizers should cater for the needs of plant growth and should opt for increases in the yields of medicinal organs and accumulations of active principles in the plants.
13. Use of domestic wastes as fertilizers should be prohibited unless these wastes are purified and can meet national standards. The use of industrial wastes, medical refuse and feces are strictly prohibited.
14. The Soil must be well aerated. In case of necessity, irrigation should take place regularly and in uniform aliquots, in order to prevent water-logging, the build-up of high microclimatic humidity and as consequence rottenness and mould formation.
15. Depending on the mode of cultivation, growers should be allowed to follow different Standard Operating Procedures.
16. Integrated pest management (IPM) should be adopted for the prevention of diseases and pests. Pesticide and herbicide application should be avoided, as far as possible. In case of necessity, smallest possible amount of high-efficacy, low-toxicity and low residue pesticides or herbicides could be used, in such a way as to minimize residues and prevent heavy metallic pollution. Only then could the safety and effectiveness of Chinese medicines be ensured and the environment be protected.

B. Raising Management of Medicinal Animals

17. Standard Operating Procedures (SOP) should be formulated according to the different properties of animals species. Special care should be taken for the needs of animal growth. The raising methods of medicinal animals should be laid down with reference to the respective habitats, feeding habits and behavioral properties. According to such methods, a system of regular raising management should be established.
18. Fodder should be formulated scientifically according to the seasonal and daily shifts in movements, the different growing periods and biological properties of the animals. Fodder vitamins, minerals and other essential additives should be replenished regularly in an appropriate amount and should be used to feed the animals regularly in an appropriate amount.
19. Regular and adequate supplies of water are vital to medicinal animals in their feeding period. And the time and frequency of water supply should be adjusted according to seasonal, temperature and ventilation changes. Herbivores should be fed with more succulence which supplies bountiful water.
20. Spacious cases should be constructed according to the special habitats and behavior of different

- animals. Devices for the prevention of fleeing should also be set.
21. Schedules for disinfecting should be laid down in order to maintain satisfying sanitary conditions. Proper medicines and disinfectants should be applied, on a regular conditions. Proper medicines and disinfectants should be applied, on a regular basis, to respective animals houses, facilities and equipment. Staff and visitors should also follow sanitation rules.
 22. The health care of medicinal animals should focus on prevention. Vaccination should be carried out regularly.
 23. Raising areas should be divided reasonably to ensure a proper spatial density for livestock that are raised together. Breeders should carefully inspect the animals, if a disease has been diagnosed, the infected animal (s) should be quarantined. In case of common diseases, separating the infected animal (s) could do, but should there be a contagious disease, the infected animal (s) should be cremated or buried deep under the ground.
 24. Appropriate plans for turnover should be formulated according to the structure and composition of the flock, which could be drawn from the production development schedules and the propagation systems.
 25. The use of animals died from toxicants or contagious diseases as raw materials for Chinese medicines should be strictly prohibited.
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V. Harvest and Primary Processing.

- 26 Harvesting of wild medicinal plants should conform to “maximum sustainable yield”. Systematic rotation and recuperation could facilitate the regeneration and propagation of wild medicinal plants.
- 27 Appropriate harvesting seasons should be determined according to the crop yield per hectare (or the number of animals bred) and quality of the products (external or internal quality), and with reference to traditional harvesting experience, seasonal changes and the manipulation of manpower.
- 28 Harvesting machines and equipment should be clean and free of contamination. They should be stored in dry, pest and rat-freed places that are out of the reach of other livestock.
- 29 In the course of harvesting, care should be taken that possible no quantities of non-medicinal materials or impurities, especially weeds or toxic matters, are mixed with the harvested crops. Damaged and perished plants should be promptly sorted out.
- 30 After harvesting, the medicinal organs of the plants should be screened, washed and processed and then dried immediately. The drying temperature should be regulated to avoid damaging the active components. Drying equipment must be maintained clean and must be regularly serviced.
- 31 Medicinal materials for fresh use should be kept under refrigeration or canned. The use of preservatives should be avoided as far as possible. In case of necessity, the use of preservatives should still conform to the Food Hygiene law of PRC.
- 32 Processing sites should include proper awning, canopy and ventilation and should also be

equipped with device against birds, pests, rodents and livestock.

- 33 Traditional processing methods for Geo-authentic medicinal materials should be well adhered to. Any alteration must be supported by sufficient experimental data.

VI. Packaging, Transportation and Storage

- 34 After a repeated control and eventual elimination of low-quality materials and foreign matters, the product should be preferable packed in uncontaminated, new, clean, dry and undamaged packaging materials.
- 35 Batch document with the following packaging information should be attached:
Product name (name of the medicinal material), batch number, specification, place of origin, manufacturing date and packaging record
- 36 The qualified label of products must be packaged in clear, permanently fixed.
- 37 Fragile products should be packaged in hard cases. Highly toxic, anesthetic and valuable medicinal materials should be put in special packages, and be sealed with appropriate labels.
- 38 In case of bulk delivery, toxic and harmful materials should be packaged separately. It is highly advisable to use aerated containers in order to keep dry and reduce the risk of mould formation of fermentation during rainy and cloudy days.
- 39 The medicinal materials should not be exposed directly to sunlight and should be stored in dry and well-aerated warehouses, which are fitted with air conditioners, dehumidifiers, concrete or similar easy to clean floors, and facilities against pests and rates. The finished products should be put on shelves and kept sufficient distance from the wall; furthermore, regular spot-check should be conducted to avoid moth, mould, rotting and oil spilling. Traditional storage method should be adopted with the combination of modernized equipment and techniques.

VII. Quality Management

- 40 The quality control unit of the production base should be responsible to the inspection and quality management in the entire course of production. It should be equipped with adequate staff, space, machines and equipment meeting the demands of the production scale and the needs of inspecting works.
- 41 The major duties of the quality control unit are:
- 1) inspecting the environment, the hygienic conditions;
 - 2) inspecting the production information, products, packaging materials and batch packages;
 - 3) drawing up the plan for GAP training and supervising its enforcement;
 - 4) managing GAP files; managing the filing of all raw data (like production records, batch documents and inspection records).
- 42 Before and after packaging, the quality control unit should examine the products by random sampling, with respect to the standards of PRC Pharmacopoeia, the enterprise and the purchasing contract. Quality tests should cover the following items: medicinal properties, impurities, water content, ash, extracts (or standard extracts), marker constituents, active constituents, residual pesticides, heavy metals and hygiene checks.
- 43 The records of quality tests have to be signed by the head of the quality control unit and the results should be stored for a minimum of 5 years.

44 Reject those products that failed the quality tests.

VIII. Personnel and Facilities

- 45 The production base should employ well-educated, properly trained and experienced, capable and responsible university graduates of pharmacy, agriculture, animal husbandry or other related majors to take charge of the overall operation.
- 46 Staff taking charge of quality inspection should at least possess high school education level. They should be responsible persons and should carry out the inspection process properly, following all the rules and regulations.
- 47 Staff engaged in the production of medicinal materials should have basic knowledge on Chinese Materia Medica, animal husbandry or agriculture and should receive training on safety, hygiene and production techniques; staff engaged in farm work should be equipped with cultivation techniques, especially the application of pesticides and related safety precautions; staff engaged in animal raising should be well equipped with raising techniques.
- 48 Staff engaged in processing, packaging, quality tests should pass the body check and those who suffer from contagious diseases, dermatosis and trauma should be kept away from the production process, all the staff should wear work apparels and gloves at work.
- 49 All ranks of staff in the production processed should receive training and examination regularly as per the requirements of the GAP Guidelines.
- 50 Washrooms and bathroom should be provided in the production base.
- 51 Adequate laboratory devices, facilities, chemicals and reagents for testing the quality of products should be available in the production base so as to guarantee the smooth running of daily inspection. The measuring range and precision of the instruments, apparatus, measuring and weighing tools should be qualified for production and inspection needs, and should be calibrated regularly and labeled with clear performance information.

IX. Documentation

52. The product base should devise its Stand Operating Procedure (SOP) for production on quality management.

53. Every details of production, including information about:

- 1) The Plant origin;
- 2) Production processes and techniques;
 - a. Seeding (schedule, quantity and area), seedling, transplantation, fertilization (kinds, schedule, quantity and method), application pesticide, fungicide or herbicide (type, quantity and schedule), have to be documented;
 - b. Raising records, turnover, breeding records, spawning records, medical history, death reports, death certificates, statistics for health inspection, fodder combination tables, fodder consumption records, pedigree records and offspring verification of medicinal animals should be kept.
- 3) Harvesting (schedule, yield, fresh weight), processing, drying, production yield (dry weight), transportation and storage should be documented;

- 4) Meteorological information, microclimate records;
- 5) Quality evaluations of medicinal materials according to properties of the materials and test results should be organized. All raw data should be documented and attached with necessary photographs and figures.
54. Production plans, execution details, contracts and agreements should be filed and kept properly for at least five years.

X. Appendix

55. Definition of terms used in the GAP Guidelines are as follows:

- 1) Chinese Medicinal Materials refer to the raw medicinal materials (or crude drug) came from medicinal organs of plants or animals after being processed in the place of production. In the broad sense, medicinal materials include traditional Chinese medicines, herbal medicines, folk medicines, folkloric medicines, phytomedicines, and animal medicines. According to their natural properties, medicinal materials can be divided into plant medicines (or phytomedicines), animal medicines and mineral medicines.
- 2) Production base enterprise of Chinese Medicinal Materials refer to the places to conduct the cultivation of medicinal plants or raising of medicinal animals to carry out primary processing packing and storage of Chinese Medicinal Materials on a fair-sized scale.
- 3) Maximum sustainable yield principle aims at the maintenance of maximum production (yielding) quantities without doing harm to the ecological environment.
- 4) Geo-authentic medicinal materials refer to authentic traditional medicinal materials of high quality, which have special germplasm, places of origin, and require special production techniques and processing methods.
- 5) Seeds and propagation materials refer to reproduction organs (tissue, cells), mycelium, sporocarp of plants and fungus which are generally known as seeds and propagation materials.
- 6) Integrated pest management is a pest management system taking into account the integration of living things and the environment and focusing on prevention. Integrated pest management uses safe, effective, economical and easy-to-follow strategies that suit the local environment and all other various methods be they cultural, agricultural, chemical or ecological to control and minimize the damage of pests and disease. This method is both economically and environmentally sound.
- 7) Semi-wild medicinal animals and plants refer to the animals and plants originally derived from wild ones which are subjected to feeding, breeding or management.

56. The GAP guidelines are revised and interpreted by the State Drug Administration.

Translator: Chun-Tao Che, Shi-Lin Chen, Zhi-Hong Jiang

Reviewer: Rong-Han Zhou