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WHO GUIDELINE ON GACP FOR MEDICAL PLANT

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ABSTRACT

Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants (2003) provide a crucial, globally applicable framework aimed at ensuring the quality, safety, and efficacy of raw medicinal plant materials. As the global demand for herbal medicines grows, GACP addresses the risks of contamination, adulteration, and incorrect identification of raw materials at the initial production stage.

The guidelines offer comprehensive technical guidance on both agricultural cultivation (GAP) and wild collection (GCP), covering crucial areas such as plant identification, seed selection, cultivation management, sustainable harvesting techniques, post-harvest processing, and proper documentation to ensure traceability. Furthermore, the document highlights the importance of protecting endangered species and minimizing environmental impact through sustainable practices. Implementing these guidelines is recognized as the foundational step in quality assurance for herbal drug industries and serves to assist Member States in developing national standards.

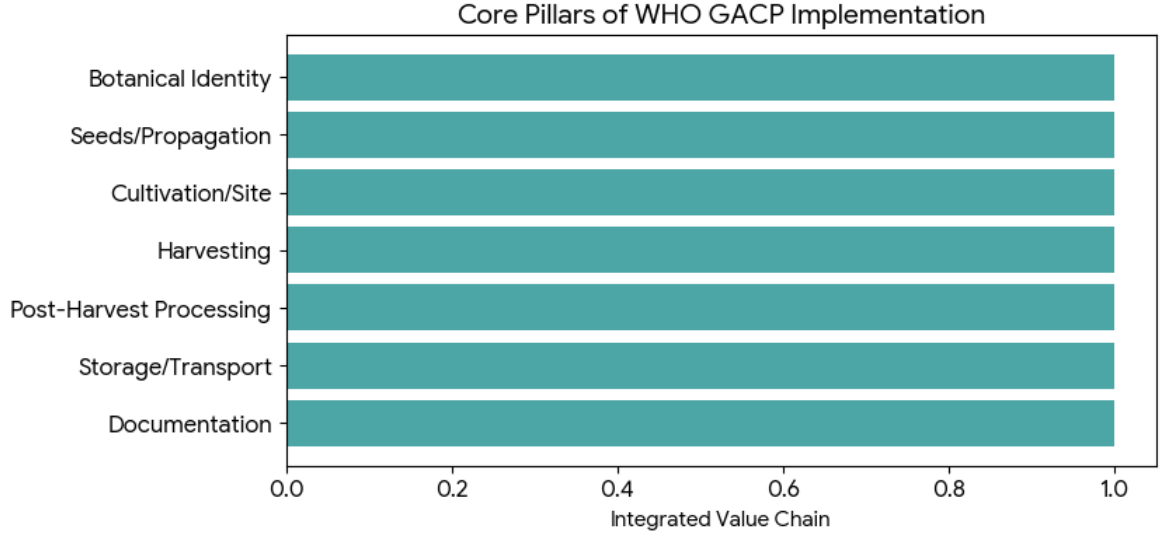
INTRODUCTION

The World Health Organization (WHO) Guidelines on Good Agricultural and Collection Practices (GACP) for medicinal plants, formulated in 2003, represent a foundational framework for ensuring the quality, safety, and efficacy of herbal raw materials. With the global increase in the use of herbal medicines, the demand for medicinal plants has risen significantly, leading to concerns regarding contamination, adulteration, and the over-exploitation of natural resources.

The GACP guidelines were developed to address these issues by providing technical guidance on the sustainable cultivation and collection of medicinal plants. They serve as the first critical step in the quality assurance of herbal products, ensuring that the raw materials meet standardized criteria from the point of cultivation or collection to post-harvest processing. The primary objectives of these guidelines are to:

- Contribute to quality assurance and enhance the safety and efficacy of finished herbal products.
- Provide a basis for regional/national guidelines and standard operating procedures (SOPs).
- Promote sustainable cultivation and environmental protection.

The guidelines cover key areas including site selection, seed identification, cultivation techniques, harvest practices, personnel training, and documentation.



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1. Objectives and Scope

The **Objectives and Scope** of the WHO Guidelines on GACP for Medicinal Plants establish the foundational quality standards for the production of herbal raw materials. They bridge the gap between initial plant sourcing and the industrial manufacturing of finished herbal medicines

1. Objectives

The primary goal is to ensure the **safety, quality, and efficacy** of finished herbal products by standardizing the first stage of production.

- **Quality Assurance**: To provide general technical guidance on obtaining high-quality medicinal plant materials for the sustainable production of herbal products.
- **Regulatory Support**: To guide Member States in formulating their own national or regional GACP guidelines and monographs.
- **Sustainable Use**: To encourage practices that respect the environment and support the conservation of medicinal plants, ensuring a steady and affordable supply.
- **Contamination Prevention**: Establishing standards to minimize risks from chemical and microbiological impurities, such as heavy metals or pesticide residues.

2. Scope

The guidelines define the boundaries and specific application areas of these practices.

- **Technical Range**: They cover the entire primary production process, including:
  - **Cultivation**: Good Agricultural Practices (GAP) for plants grown in open fields, greenhouses, or indoors.
  - **Wild Collection**: Good Collection Practices (GCP) for plants harvested from their natural habitats.
  - **Post-Harvest Operations**: Primary processing such as drying, cutting, bulk packaging, and storage.
- **Product Definition**: They apply specifically to medicinal plant materials used for herbal products classified as **medicines**.
- **Exclusions**: While they touch on early processing, they generally stop where large-scale industrial manufacturing—governed by **Good Manufacturing Practices (GMP)**—begins.

2. Good Agricultural Practices (GAP)

Good Agricultural Practices focus on the controlled cultivation of medicinal plants to ensure high-quality raw materials that are free from contamination and consistent in their therapeutic properties.

2.1 Key Components of GAP

- **Identification and Authentication**: Selection of the correct botanical identity (genus, species, variety/cultivar). Voucher specimens must be deposited in a regional or national herbarium for reference.
- **Seeds and Propagation Material**: Use of high-quality, disease-free seeds or vegetative propagation materials. The origin of the material must be traceable and, if possible, certified.
- **Site Selection and Environment**: Cultivation sites should be free from hazardous soil, water, or air pollution (e.g., heavy metals, pesticides, or industrial waste). Climate and soil type must be suitable for the specific species.

- **Crop Management**
  - **Irrigation**: Water must be clean; untreated sewage or contaminated water is strictly prohibited.
  - **Fertilization**: Use of chemical or organic fertilizers must be documented. Human excreta is prohibited.
  - **Pest Management**: Integrated Pest Management (IPM) is preferred. If pesticides are used, they must comply with national regulations and leave minimal residues.
- **Harvesting**: Plants should be harvested during the optimal season or growth stage to ensure peak concentration of active constituents. Equipment must be clean and well-maintained.

2.2 Documentation and Quality Control

Detailed field records must be maintained for every batch, including:

- Location and history of the land.
- Types and quantities of fertilizers or pesticides applied.
- Dates of planting and harvesting.
- Names of personnel involved in the cultivation process.

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Summary of GAP Requirements	
Feature	**Requirement**
Botanical Identity	Verified scientific name and voucher specimen.
Soil/Water	Free from heavy metals, pesticides, and microbial pathogens.
Maintenance	Documented use of fertilizers; no human waste allowed.
Harvest Timing	Based on optimal medicinal potency (active ingredients).

3. Good Collection Practices (GCP)

Good Collection Practices (GCP) apply to medicinal plants sourced from their natural habitats. These guidelines ensure that wild harvesting is conducted sustainably, ethically, and without compromising the botanical integrity or quality of the raw material.

3.1 Planning and Permissions

- **Regulatory Compliance**: Collectors must obtain all necessary government permits and land-use authorizations before harvesting.
- **Conservation Status**: National "red lists" of endangered species and CITES appendices must be consulted to ensure that harvesting does not involve prohibited or critically threatened species.
- **Technical Planning**: Harvesting should be planned according to the optimal season and growth stage to maximize the content of active constituents.

3.2 Selection and Identification

- **Botanical Verification**: The species, genus, and variety must be accurately identified to prevent the inclusion of morphologically similar but toxic or inert plants.
- **Voucher Specimens**: Collectors should prepare and submit botanical specimens to regional or national herbaria for authentication and long-term record-keeping.

3.3 Sustainable Harvesting Methods

- **Resource Perpetuation**: Harvest levels must be set to allow for natural regeneration and the long-term survival of the wild population.
- **Minimal Environmental Impact**: Techniques should not damage the surrounding habitat or the growth environment of the parent plant.
- **Selective Collection**: Only healthy, target plant parts (roots, leaves, fruits, etc.) should be collected, leaving behind diseased or immature specimens.

3.4 Personnel and Welfare

- **Training**: Field personnel must be trained in botanical identification, sustainable harvest techniques, and basic hygiene.
- **Safety**: Workers must be provided with protective clothing to guard against toxic plants, disease-carrying insects, or poisonous animals.

3.5 Documentation

Detailed records must be maintained for each collection event, including:

- **Geographical Location**: The exact country and region/area of collection.
- **Collection Details**: Type and quantity of material, date/period of collection, and the names of the collectors.
- **Traceability**: Each batch must be assigned a unique number to allow it to be traced back to its specific source.

Technical Aspects of Post-Harvest Processing

Technical Aspects of Post-Harvest Processing

The WHO guidelines define post-harvest management as the handling of medicinal plant produce from the moment of harvest until it is ready for sale or further use. Key technical operations include:

- **Primary Processing (Immediate Handling):**
  - Washing (using potable water), cutting, sorting, peeling, squeezing, and grading.
  - Processing should occur as soon as possible after harvesting to prevent spoilage.
  - Mechanical damage or compacting of raw materials (e.g., overfilling sacks) must be avoided to prevent composting or loss of quality.
- **Drying:**
  - Crucial for inhibiting microbial growth and enzymatic activity, thereby extending shelf life.
  - Materials may be dried in the shade or initially under sunlight, depending on the plant part.
  - Fleshy or large materials should be sliced into smaller pieces to facilitate even and efficient drying.

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- **Hygiene and Sanitation:**
  - All equipment, tools (machetes, shears), and containers must be **"spotlessly clean"** and regularly maintained to prevent cross-contamination.
  - Processing facilities must be well-aerated, protected from pests (birds, insects, rodents), and never used for housing livestock.
- **Bulk Packaging and Labelling:**
  - Early packaging is advised to reduce pest attacks.
  - Labels must be clear, permanent, and use non-toxic inks.
- **Storage and Transport:**
  - Fresh materials should ideally be stored at 2°C–8°C.
  - Packaged dry materials require a dry, well-ventilated building with concrete or easy-to-clean floors.
  - Materials should be stored on pallets or racks, away from walls and the roof, to avoid moisture absorption and allow airflow.

Regulatory and Personnel Requirements

- **Traceability:** A robust documentation system must be in place to trace plant material back to its exact origin.
- **Personnel Training:** All handlers must receive training in personal hygiene and the specific botanical identification of the plants they process. Persons with infectious diseases or open wounds must be suspended from handling areas.

Quality Control and Standardization

In the context of the **WHO Guidelines on GACP**, Quality Control (QC) and Standardization are the mechanisms used to ensure that the medicinal plant material meets defined safety and efficacy benchmarks before it enters the supply chain.

Technical Requirements for QC and Standardization

According to the guidelines, the primary objective is to verify the identity, purity, and quality of the raw material.

- **Botanical Identification and Authentication:**
  - The identity of the plant species (Latin binomial name, including genus, species, and author) must be verified.
  - Macroscopic (visual) and microscopic (cellular) examinations are used to ensure no substitution or adulteration with similar-looking species.

- **Physicochemical Analysis:**
  - **Foreign Matter:** Samples must be inspected for dirt, stones, and non-target plant parts. WHO limits are strictly enforced.
  - **Moisture Content:** Crucial for preventing fungal growth. Standardization requires specific drying loss limits (usually determined by oven drying or Karl Fischer titration).
  - **Ash Values:** Total ash and acid-insoluble ash tests are conducted to detect earthy matter or inorganic minerals.

- **Phytochemical Standardization:**
  - Testing for **active constituents** or marker compounds using techniques like High-Performance Liquid Chromatography (HPLC) or Gas Chromatography (GC).
  - This ensures the batch has the expected therapeutic potency.

- **Safety Testing (Contaminants):**
  - **Pesticide Residues:** Testing for organochlorine and organophosphorus pesticides based on WHO/FAO standards.
  - **Heavy Metals:** Strict limits on Lead (Pb), Cadmium (Cd), Mercury (Hg), and Arsenic (As).
  - **Microbial Load:** Analysis for total aerobic microbial count (TAMC) and specific pathogens like *E. coli* or *Salmonella*.
  - **Aflatoxins/Mycotoxins:** Essential for plants prone to mold during storage.

Documentation and Compliance

- **Batch Documentation:** Each batch requires a **Certificate of Analysis (CoA)** detailing all results against the specifications.
- **Reference Samples:** A "voucher specimen" (a representative sample from the batch) must be retained for a defined period for future verification or in case of quality disputes.

Technical Requirements for Documentation

Every stage of the process must be recorded in real-time. The guidelines emphasize that "if it isn't written down, it didn't happen."

- **Standard Operating Procedures (SOPs):** Detailed, written instructions must exist for all activities, including cultivation, harvesting, drying, and storage. These ensure consistency across different batches and personnel.

- **Field/Collection Records:**
  - **Cultivation:** Records must include the history of the land (previous crops, pesticide use), the source of seeds/propagules, and the dates of irrigation, weeding, and fertilization.

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- **Wild Collection:** Collectors must record the exact geographical location (often via GPS), the habitat type, and the quantity collected to ensure environmental sustainability.
- **Batch Records:** Every "lot" or "batch" of material must have a unique identification number. This number follows the material from the field to the processing facility and finally to the consume

Traceability Mechanisms

Traceability ensures that any batch of medicinal plant material can be identified at any point in the supply chain.

- **Labels:** All containers must be clearly labeled with the botanical name, part of the plant, batch number, date of harvest, and origin. Labels must be durable and resistant to environmental conditions.
- **Inventory Logs:** Storage facilities must maintain "First-In, First-Out" (FIFO) or "First-Expired, First-Out" (FEFO) records to prevent old material from being buried under new stock.
- **Audit Trails:** Internal audits must be conducted periodically to verify that the documentation matches the physical stock. Any discrepancies or "out-of-specification" results must be documented with a corrective action plan.

Personnel and Training Records

- Logbooks must track which individuals performed specific tasks (e.g., who applied a specific fertilizer or who performed the final quality check).
- Training files for each staff member must be maintained to prove they are qualified for their specific roles in GACP.

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Technical Requirements for Personnel and Training

The guidelines focus on three main areas: expertise, health, and continuous education.

- **Technical Expertise & Education:**
  - **Botanical Knowledge:** Personnel (especially wild collectors) must be able to identify the target plant with absolute certainty and distinguish it from poisonous or related "look-alike" species.
  - **Qualified Supervisors:** Managers overseeing cultivation or collection should have a recognized degree or technical experience in agronomy, botany, or pharmaceutical sciences.

- **Health and Hygiene**
  - **Medical Fitness:** All staff must undergo a medical examination before employment.
  - **Contamination Control:** Any person with an infectious disease (e.g., respiratory infections) or open skin lesions must be excluded from handling plant materials until they are fully recovered to prevent microbial contamination.
  - **Protective Clothing:** Personnel must wear clean work clothes, including gloves and headcovers where necessary, to protect both themselves and the medicinal material.

- **Structured Training Programs**
  - **GACP Principles:** Staff must be trained in the specific "whys" behind the guidelines, such as why drying temperatures must be controlled or why tools must be cleaned.
  - **Safety Training:** Instruction on the safe use of agricultural chemicals (pesticides/herbicides) and the operation of processing machinery.
  - **Record Keeping:** Training on how to accurately fill out logbooks and batch records to maintain the **Traceability** discussed earlier.

Management Responsibilities

- **Training Records:** Management must maintain individual files for every employee, documenting every training session attended and the date it was completed.
- **Periodic Refreshers:** Training is not a one-time event; regular "refresher" courses are required to keep staff updated on new safety standards or botanical risks.

Ethical and Legal Requirements (The Social Contract)

This section ensures that the medicinal plant industry does not exploit people or sovereign resources.

- **Access and Benefit Sharing (ABS):** Under the **Nagoya Protocol**, if a company uses a plant found in a specific region (e.g., a rare herb from the Himalayas), they must have a legal agreement with the local community or government. They cannot simply take the plant and profit; they must share a portion of the benefits (financial or technical) with the providers.
- **Protection of Traditional Knowledge:** Many medicinal plants are used based on centuries of indigenous wisdom. GACP requires that this "intellectual property" of local healers be respected. You cannot patent a traditional use without proper legal clearance.
- **Fair Labor Practices:** This involves more than just wages. It includes providing **Personal Protective Equipment (PPE)** for workers handling toxic plants (like *Aconitum*) and ensuring that no child labor is used in the collection or sorting process.

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2. Environmental and Sustainability Considerations (Ecological Security)

Medicinal plants are often over-exploited. This section acts as a technical "stop-gap" to prevent extinction.

- **Sustainable Harvesting Yields:** For wild-collected plants, GACP mandates a **"Non-Detriment Finding."** This means you must prove that taking the plant won't kill off the local population. For example, if you harvest roots, you must leave a percentage of reproductive plants in the ground to reseed.
- **Biodiversity & Genetic Erosion:** GACP discourages "monocultures" that destroy local ecosystems. It encourages the preservation of "wild types" to maintain genetic diversity, which makes plants more resistant to pests naturally.
- **Chemical Stewardship:** While GACP allows for some fertilizers/pesticides, it prioritizes **Integrated Pest Management (IPM)**. This means using natural predators or organic barriers first to prevent chemical runoff into the local water table, which would harm both the environment and the final medicinal quality.

3. Conclusion and Future Perspectives (The Road Ahead):-

The conclusion of the WHO guidelines looks at how the industry must evolve to survive a changing world.

- **Technological Traceability (Industry 4.0):** The future is moving toward **Blockchain-enabled supply chains**. This allows a consumer to scan a QR code on a bottle of herbal medicine and see exactly which farm (and which worker) harvested the raw material three months prior.
- **Climate Change Adaptation:** As global temperatures rise, the "secondary metabolites" (the medicinal parts) of plants are changing. Future GACP will focus on **precision agriculture**—using sensors to ensure plants are grown in optimal stress conditions to produce the highest therapeutic yield despite a changing climate.
- **Global Standardization:** There is a push to make WHO GACP the "Universal Language." Currently, a plant grown under Indian GACP might face hurdles in Europe; the future goal is a single, globally accepted certification that allows seamless trade.

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